



in DAC

HAND DELIVER RECEIPT

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

I HEREBY CERTIFY THAT THIS
CORRESPONDENCE IS BEING
HANDDELIVERED BY ANNETTE
MASIELLO TO THE UNITED STATES
PATENT AND TRADEMARK OFFICE ON:

June 7, 2007
Date

By Annette Masiello
Signed,

A. Masiello
A. Masiello

1. Petition for the Correction of Claim of Benefit (3 pages) — *Expedited Request*
2. Supplemental Application Data Sheet (4 pages)
3. Initial Information Data Sheet (3 pages)
4. Filing Receipt dated 4/11/02 (2 pages)
5. Corrected Filing Receipt dated 3/16/06 (3 pages)
6. Office communication dated 7/8/03 (9 pages)
7. Response to Office communication dated 1/8/04 (41 pages)
8. Office communication dated 4/23/04 (9 pages)
9. Response to Office communication dated 10/21/04 (24 pages)
10. After-Final Amendment dated 3/13/06 (19 pages)
11. Request for Correction of Filing Receipt dated 3/15/06 (6 pages)
12. Advisory Action dated 4/11/06 (4 pages)
13. Request for Correction of Filing Receipt dated 10/6/06 (5 pages)
14. Notice of Allowance dated 1/24/07 (12 pages)
15. Request for Certificate of Correction cover letter (2 pages)
16. Request for Certificate of Correction, Form PTO/SB/44 (1 page)



Expedited Petition

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Himmelsbach, Frank et al.) Art Unit: 1624
U.S. Patent No. : 7,220,750) Examiner: Truong, Tamthom N.
Issue Date : May 22, 2007
U.S. Appln. No. : 10/016,280
U.S. Filing Date : December 10, 2001
Title of Invention : Bicyclic Heterocycles, Pharmaceutical Compositions containing these
Compounds, Their Use and Processes for Preparing Them
Attny. Docket No.: 5/1262

June 6, 2007

Commissioner for Patents
Mail Stop Petitions
Alexandria, VA 22313-1450

PETITION FOR THE CORRECTION
OF THE CLAIM OF BENEFIT UNDER 37 CFR § 1.78

Sir:

Applicants respectfully petition for the correction of the claim of benefit for U.S. Patent No. 7,220,750 issued on May 22, 2007. Attached hereto is a Supplemental ADS form with the correct claim to benefit. Applicants' attorney respectfully requests expedited treatment of this petition.

The present patent is a continuation of International Application No. PCT/EP00/05547, filed on June 16, 2000, which claimed the benefit of U.S. Provisional Application No. 60/146,644, filed on July 30, 1999, and two Germany applications, DE199280281.1 and DE10023085.7, filed June 21, 1999 and May 11, 2000, respectively.

U.S. Patent Application No. 10/016,280, which was issued as U.S. Patent No. 7,220,750 on May 22, 2007, was filed on December 10, 2001 with an ADS that indicated it was to be a nationalized application under 35 U.S.C. § 371 of International Application No. PCT/EP00/05547, filed June 21, 2000, and claimed the benefit of U.S. Provisional Application No. 60/146,644, filed on July 30, 1999. However, Applicants' attorney

mistakenly used the wrong transmittal forms, and thus, the application was treated as a continuing application filed under 35 U.S.C. § 111(a). Attached is a copy of the ADS as originally filed (Tab A), the Filing Receipt as issued (Tab B) and the later issued Corrected Filing Receipt (Tab C).

The claim of benefit to the international application and the earlier filed provisional application was repeated in the Declaration which was filed on April 25, 2002. In an Office Action dated July 8, 2003, the Examiner acknowledged receipt of certified copies of the priority documents, but indicated that the specification needed to be amended to recite the relationship of the application to the prior filed applications, as well as a claim of benefit thereto. In a response to this action, Applicants' attorney amended the specification to recite the relationship of the pending application to the earlier filed international application. Attached are copies of said action and Applicants' response thereto (Tabs D and E, respectively).

In a subsequent action dated April 23, 2004, the Examiner acknowledged a claim of benefit to the U.S. Provisional Application No. 60/146,644, filed July 30, 1999, but requested that certified copies of the German applications be submitted. In response to this action, Applicants submitted the certified copies of the Germany applications on October 21, 2004. Attached are copies of the action dated April 23, 2004 and Applicants' response thereto (Tabs F and G, respectively).

Subsequently, Applicants' attorney filed an after-final amendment on March 13, 2006, and therein restated the claim of benefit to the earlier filed applications and requested that the Examiner acknowledge the priority claim. Applicants' attorney also filed a request for a corrected filing receipt in order to correct the claim of benefit on March 15, 2006. In an Advisory Action dated April 11, 2006, the Examiner acknowledged receipt of the certified Germany applications. Attached are copies of the After-Final Amendment, Request for a Corrected Filing Receipt and the Advisory Action (Tabs H, I and J, respectively).

On October 6, 2006, Applicants' attorney filed an RCE and another request to correct the priority data on the Filing Receipt. A Notice of Allowance was issued on January 24, 2007 and attached thereto was an Examiner's amendment, which amended the specification to

claim the benefit of only the international application. On April 12, 2007, the issue fee was paid. Copies of the second request for a corrected Filing Receipt are attached as well as a copy of the Notice of Allowance (Tabs K and L, respectively).

Based upon the facts as recited above, and evidenced by the attached documents, Applicants' attorney respectfully submits that the delay in attempting to correct the claim of benefit was unintended. Applicants' attorney has also paid the required fee under 37 CFR § 1.17(t) for unintentional delay. Applicants' attorney has also submitted a Supplemental ADS, which correctly identifies U.S. Patent Application No. 10/016,280 as a continuing application of International Patent Application No. PCT/EP00/05547.

The undersigned hereby requests that the Deputy Commissioner for Patent Examination Policy grant this petition.

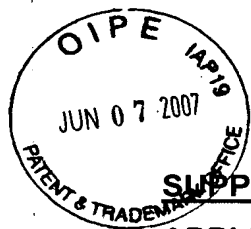
The Commissioner is hereby authorized to charge any fees due in connection with this Petition for the Correction of the Claim of Benefit Under 37 CFR § 1.78 to Deposit Account No. 02-2955.

Respectfully submitted,



Mary-Ellen M. Devlin, Reg. No. 27,928
Attorney for Applicant(s)

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road, P.O. Box 368
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Tel: (203) 798-4866
Date: June 6, 2007



SUPPLEMENTAL APPLICATION DATA SHEET

APPLICATION INFORMATION

Application Number::	10/016,280
Filing Date::	December 10, 2001
Application Type::	Regular
Subject Matter::	Utility
CD-ROM or CD-R?::	None
Number of CD disks::	0
Number of copies of CDs::	0
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Number of copies of CRF::	0
Title::	Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them
Attorney Docket Number::	5/1262
Request for Early Publication?::	No
Request for Non-Publication?::	No
Suggested Drawing Figure::	0
Total Drawing Sheets::	0
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

APPLICANT INFORMATION

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Country of mailing address:: Austria
Postal or Zip Code of mailing address:: A-1050

CORRESPONDENCE INFORMATION**Correspondence Customer Number::** 28505**REPRESENTATIVE INFORMATION****Representative Customer Number::** 28505**DOMESTIC PRIORITY INFORMATION**

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	Continuation	PCT/EP00/05547	06/16/2000
PCT/EP00/05547	an application claiming the benefit under 35 USC 119(e)	60/146,644	07/30/1999

FOREIGN PRIORITY INFORMATION

Country::	Application Number::	Filing Date::	Priority Claimed::
DE	199 28 281.1	06/21/1999	Yes
DE	100 23 085.7	05/11/2000	Yes

ASSIGNEE INFORMATION

Assignee name:: Boehringer Ingelheim Pharma GmbH Co. KG
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City of mailing address:: Ingelheim
Country of mailing address:: Germany
Postal or Zip Code of mailing address:: 55216



INITIAL INFORMATION DATA SHEET

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Postal or Zip Code:	1020
Citizenship Country:	AT

Correspondence Information:**Customer Number or Barcode Label:****Application Information:**

Title Line One:	Bicyclic Heterocycles, pharmaceutical
Title Line Two:	compositions containing these compounds,
Title Line Three:	their use and processes for preparing them
Total Drawing Sheets:	0
Formal Drawings?:	N/A
Application Type:	Utility
Docket No.:	5/1262

Continuity Information:

This application is a:	Non-Provisional of Provisional
>Application One:	60/146,644
Filing Date:	July 30, 1999

This application is a:	371of
>Application Two:	PCT/EP00/05547
Filing Date:	June 21, 1999

Prior Foreign Applications:

Foreign Application One:	199 28 281.1
Filing Date:	June 21, 1999
Country:	DE
Priority Claimed:	Yes

Foreign Application Two:
Filing Date:
Country:
Priority Claimed:

100 23 085.7
May 11, 2000
DE
Yes



TXW

d



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/016,280	12/10/2001	1619	1038	5/1262		11	1

CONFIRMATION NO. 7351

28505
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877

FILING RECEIPT



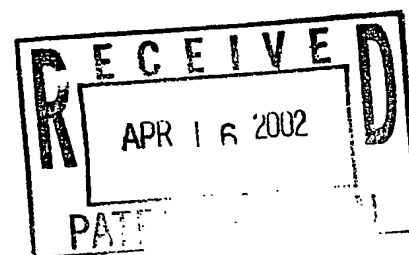
OC000000007851317

Date Mailed: 04/11/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Frank Himmelsbach, Mittelbiberach, GERMANY;
Elke Langkopf, Warthausen, GERMANY;
Thomas Metz, Wien, AUSTRIA;
Flavio Solca, Wien, AUSTRIA;
Birgit Jung, Schwabenheim, GERMANY;
Anke Baum, Wien, AUSTRIA;



Domestic Priority data as claimed by applicant

THIS APPLN CLAIMS BENEFIT OF 60/146,644 07/30/1999

Foreign Applications

GERMANY 199 28 281.1 06/21/1999
GERMANY 100 23 085.7 05/11/2000

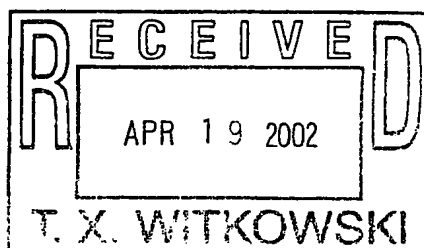
If Required, Foreign Filing License Granted 04/10/2002

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title



Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them

Preliminary Class

424

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/016,280	12/10/2001	1624	1438	5/1262		11	1

CONFIRMATION NO. 7351

CORRECTED FILING RECEIPT



OC000000018304916

28505
MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

Date Mailed: 03/16/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Frank Himmelsbach, Mittlbiberach, GERMANY;
Elke Langkopf, Warthausen, GERMANY;
Thomas Metz, Wien, AUSTRIA;
Flavio Solca, Wien, AUSTRIA;
Birgit Jung, Schwabenheim, GERMANY;
Anke Baum, Alland, AUSTRIA;

MAR 20 2006

Power of Attorney:

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Alan Stempel-28991
Timothy Witkowski-40232
Philip Datlow-41482

Anthony Bottino-41629
Susan Pocchiari-45016

Domestic Priority data as claimed by applicant

This application is a CON of PCT/EP00/05547 06/16/2000

Foreign Applications

GERMANY 199 28 281.1 06/21/1999
GERMANY 100 23 085.7 05/11/2000

If Required, Foreign Filing License Granted: 04/10/2002

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/016,280**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them

Preliminary Class

544

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



UNITED STATES PATENT AND TRADEMARK OFFICE

d SKP

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351

28505 7590 07/08/2003

BOEHRINGER INGELHEIM CORPORATION
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P. O. BOX 368
RIDGEFIELD, CT 06877

EXAMINER

PATEL, SUDHAKER B

ART UNIT PAPER NUMBER

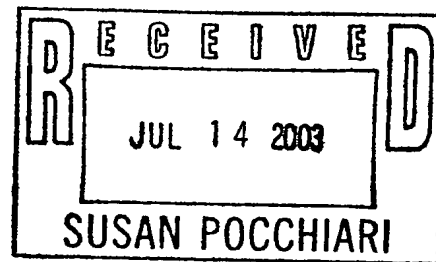
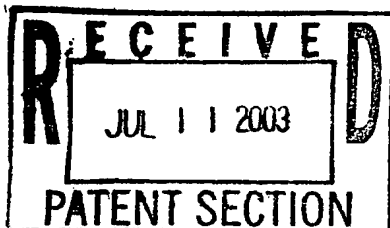
1624

DATE MAILED: 07/08/2003

10-8-03

1-08-04 LAST DAY

Please find below and/or attached an Office communication concerning this application or proceeding.





Office Action Summary

Application No.

10/016,280

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Applicants' communication paper # 7 dated 6/4/03 is acknowledged.

Election/Restrictions

1. Because applicants did not distinctly and specifically point out the supposed errors in the restriction/election requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Applicants have elected species of generic Formula (I) of claim 1, namely, compound of Example 3 recited in page 44 lines 20-22 (= 4-[(3-Chloro-4-fluorophenyl)amino]-6-[[4-(N,N-diethylamino)-oxo-2-buten-1-yl]amino]-7-cyclopropylmethoxyquinazoline), claims (in part) 1-11, drawn to compounds, compositions, method of use, and the first recited process of making the same for the generic Formula (I).

Applicants are reminded of the election of species guidelines provided in MPEP 803.02, which are followed for the examination.

The elected species of compound of Example 3 as stated earlier has following meanings for variables in the generic Formula (I) of claim 1:

X	= N;
A	= imino(= -NH-);
B	= -CO-;
C	= 1,2-vinylene(= -CH=CH-);
D	= methylene (= - CH ₂ -);
E	= diethylamino;
Ra	=H;
Rb	=phenyl substituted by R1 = H, R2 = F, in 4 position of phenyl, and R3 = Cl in 3-position of phenyl;
Rc	=-O-(alkyl)-cycloalkyl (= cycloalkyl-alkoxy-).

Art Unit: 1624

Initial search with above definitions of the variables for the species did reveal prior art(s). Therefore, the search was limited to meanings of variables as stated above. All other definitions of variables than stated above are excluded from further consideration. 37 CFR 1.142(b).

This application has been found to contain more than one invention. Therefore, the requirement is still deemed proper and is therefore maintained.

First action on merits follows.

2.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Germany on 6/21/1999. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

3. It is noted that this application appears to claim subject matter disclosed in prior Application No. 60146644, filed 7/30/1999. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on

which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

3. The disclosure is objected to because of the following informalities: The continuity information recited as :” This application is a 371 of PCT/EP00/05547 filed 6/21/1999” is not proper. The Office record for this application does not indicate the relationship between the above stated applications, namely, the U.S. Provisional Application Sr. No. 60/14664 filed 7/30/199; The PCT/EPOO/05547 filed 6/21/1999; DE 19928281.1 filed 6/21/1999, and DE10023 085.7 filed 5/11/2000.

Appropriate correction is required.

Claims objections

4. Claims 8-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 7. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A). Claims 1-5 recite: "Bicyclic heterocycles of general Formula: Correction to A quinqzoline compound of Formula". Is required.

(B). Claims 1-5 recite (where applicable) at the end of the claims: "the tautomets, stereoisomers and salts thereof". Such recitation includes other compounds/mixtures those are not claimed. Correction to: "or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof" is required.

(C). Claim 6 recites specific compounds and is ending as: "as well as the salts thereof". It is not very clear as to what applicants want to claim. The recitation includes mixture of compound also. Correction to: "or pharmaceutically acceptable salts thereof" is required.

(D). Claim 7 recites: "Physiologically acceptable salts of the compounds... to at least one of claims". Correction to Pharmaceutically acceptable salts of the compounds of claims 1 to 6..." is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker A. J. (EP 566226, also cited as Chemical Abstract DN 120:217715) as applied to claims above, and further in view of Bridges et al (WO 9738983).

Applicants are claiming substituted quinazolines, pharmaceutical compositions, and their use as inhibitors of Tyrosine kinase for treating diseases consisting of tumoral diseases, diseases of lungs and respiratory tract and others.

Ref. '226 is teaching making of quinazoline tyrosine kinase-inhibiting anticancer agents.

The ref. '226 chemical core is:

4,6-Quinazolinediamine, 7-methoxy-N-4-(3methylphenyl). See compound having CAS RN # 153437-18-4.

The ref. '226 differs from the instant claims by having CH₃-O- instead of -O-CH₂-Cycloalkyl, and -NH₂ instead of -NH-CO-CH=CH-CH₂-N(alkyl)₂.

The other ref. '983 teaches making of irreversible inhibitors of tyrosine kinase. See compound of Example 55 on page 123, and the compounds of claim 1. on pages 152-154.

The ref. '983 teaches modification(s) of the 6-NH₂ group to -NH-CO-CH=CH-CH₂-N(alkyl)₂ or NH-CO-CH=CH-CH₂-NH₂ or NH-CO-CH=CH-CH₂-NH(alkyl) as claimed herein.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference 'Barker i.e. substituted quinazoline with free 6-NH₂ and condense with maleic anhydride to get -NHCO-CH=CH-COOH, and modify the end group as taught by ref. ' 983 because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as the genus as a whole.

The 4-phenyl-substituted quinazoline derivatives were known prior to 6/21/1999.

Also modification of 6-NH₂ group on to quinazolines were known, and compounds so obtained are having pharmacological activity as inhibitors of Tyrosan Kinase.. This pharmaceutical activity has been retained by compounds of both of the references.

It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Mark & Co. V.s. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1943, 1846 (Fed. Cir. 1989).

Applicants are claiming their compounds as novel. However, they are differing by having cycloalkyl instead of alkyl substitution on to 7-OH group of quinazoline and such compounds involve close structural similarity with the prior art(s) as cited above. The 6-membered N-contain ring will provide isomers with 2 N atoms participating with a double bond either between themselves or with adjacent carbon atom(s). Applicants have not shown that their novel useful compounds, which are structurally similar to prior art(s), possessed some unobvious or unexpected beneficial property not possessed by the prior art compound(s). In re Norris (CCPA 1950) 179 F2 970, 84 USPQ 458.

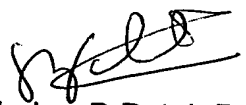
Conclusion


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709.

The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.


Sudhaker B. Patel, D.Sc.Tech.
July 1, 2003.


MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Himmelsbach, F. et al) Art Unit: 1624
Serial No. : 10/016,280) Examiner: Patel, S.
Confirmation No. : 7351
Filed : December 10, 2001
For : Bicyclic heterocycles, pharmaceutical compositions
containing these compounds, their use and processes
for preparing them
Docket No. : 5/1262

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY WITH AMENDMENT UNDER 37 U.S.C. § 1.111

Sir:

In response to the Office Action mailed on July 8, 2003, please consider the remarks and enter the amendments below. Submitted herewith is: (a) a Petition for Extension of Time for three months up to and including January 8, 2004, together with the necessary fee; (b) a copy of the Declaration for Utility or Design Application, in three counterparts; and (c) a new Application Data Sheet.

Amendments to the specification begin on page 2 of this paper.

Amendments to the claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks begin on page 22 of this paper.

Amendments to the Specification:

Please add the following new paragraph after the title on page 1:

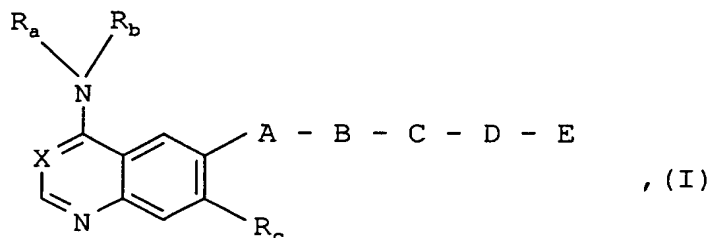
This application is a continuation of International Application PCT/EP00/05547 (WO 00/78735) filed on June 16, 2000 which claims benefit to prior U.S. Provisional Application 60/146,644, filed July 30, 1999 and prior German Application Nos. DE 199 28 281 and DE 100 23 085, filed June 21, 1999 and May 11, 2000, respectively. Benefit of the earlier filing date of the prior International Application is hereby claimed pursuant to 35 U.S.C. § 365(c).

Amendments to the Claims:

This listing of claims will replace all prior versions and listing of claims in the application:

Listing of Claims:

1. (currently amended) ~~Bicyclic heterocycles~~ A quinazoline compound of general formula



wherein

R_a denotes a hydrogen atom or a C₁₋₄-alkyl group,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ to R₃, whilst

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C₁₋₄-alkyl, hydroxy, C₁₋₄-alkoxy, C₃₋₆-cycloalkyl, C₄₋₆-cycloalkoxy, C₂₋₅-alkenyl or C₂₋₅-alkynyl group,

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a C₃₋₅-alkenyloxy or C₃₋₅-alkynyloxy group, whilst the unsaturated moiety may not be linked to the oxygen atom,

a C₁₋₄-alkylsulfenyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, C₁₋₄-alkylsulfonyloxy, trifluoromethylsulfenyl, trifluoromethylsulfinyl or trifluoromethylsulfonyl group,

a methyl or methoxy group substituted by 1 to 3 fluorine atoms,

an ethyl or ethoxy group substituted by 1 to 5 fluorine atoms,

a cyano or nitro group or an amino group optionally substituted by one or two C₁₋₄-alkyl groups, wherein the substituents may be identical or different, or

R₁ together with R₂, if they are bound to adjacent carbon atoms, denote a - CH=CH-CH=CH-, ~~CH=CH-NH~~ or ~~CH=N-NH~~ group and

R₃ denotes a hydrogen, fluorine, chlorine or bromine atom,

a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,

X denotes ~~a methine group substituted by a cyano group or a nitrogen atom,~~

A denotes an imino group optionally substituted by a C₁₋₄-alkyl group,

B denotes a carbonyl ~~or sulfonyl~~ group,

C denotes a 1,3-allenylene, 1,1- or 1,2-vinylene group which may be substituted in each case by one or two methyl groups or by a trifluoromethyl group,

an ethynylene group or

a 1,3-butadien-1,4-ylene group optionally substituted by 1 to 4 methyl groups or by a trifluoromethyl group,

D denotes an alkylene, ~~CO-alkylene or SO₂-alkylene~~ group wherein the alkylene moiety in each case contains 1 to 8 carbon atoms and additionally 1 to 4 hydrogen atoms in the alkylene moiety may be replaced by fluorine atoms, whilst the linking of the ~~CO-alkylene or SO₂-alkylene~~ group to the adjacent group C in each case must take place via the carbonyl or sulfonyl group,

~~a CO-O alkylene, CO-NR₄-alkylene or SO₂-NR₄-alkylene group wherein the alkylene moiety in each case contains 1 to 8 carbon atoms, whilst the linking to the adjacent group C in each case must take place via the carbonyl or sulfonyl group, wherein~~

~~R₄ denotes a hydrogen atom or a C₁₋₄-alkyl group,~~

~~or, if D is bound to a carbon atom of the group E, it may also denote a bond~~

~~or, if D is bound to a nitrogen atom of the group E, it may also denote a carbonyl or sulfonyl group,~~

E denotes an amino, C₁₋₄-alkylamino or di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

a C₂₋₄-alkylamino group wherein the alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst

R₅ denotes a hydroxy, C₁₋₄-alkoxy, amino, C₁₋₄-alkylamino or di-(C₁₋₄-alkyl)-amino group,

~~a 4 to 7 membered alkyleneimino group optionally substituted by one or two methyl groups or~~

~~a 6 to 7 membered alkyleneimino group optionally substituted by one or two methyl groups wherein in each case a methylene group in position 4 is replaced by an oxygen or sulfur atom, by a sulfinyl, sulfonyl, imino or N-(C₁₋₄-alkyl) imino group,~~

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst R₅ is as hereinbefore defined,

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties are substituted in each case in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst the substituents may be identical or different and R₅ is as hereinbefore defined,

a C₃₋₇-cycloalkylamino or C₃₋₇-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom may be substituted by a further C₁₋₄-alkyl group,

~~an amino or C₁₋₄-alkylamino group wherein in each case the nitrogen atom is substituted by a tetrahydrofuran-3-yl, tetrahydropyran-3-yl, tetrahydropyran-4-yl, tetrahydrofuranylmethyl, 1-(tetrahydrofuran-3-yl) piperidin-4-yl, 1-(tetrahydropyran-3-yl) piperidin-4-yl, 1-(tetrahydropyran-4-yl) piperidin-4-yl, 3-pyrrolidinyl, 3-piperidinyl, 4-piperidinyl, 3-hexahydro-azepinyl or 4-hexahydro-azepinyl group optionally substituted by 1 to 3 C₁₋₄-alkyl groups;~~

~~a 4- to 7-membered alkyleneimino group optionally substituted by 1 to 4 C₁₋₂-alkyl groups, which may be substituted by the group R₅ either at a cyclic carbon atom or at one of the alkyl groups, whilst R₅ is as hereinbefore defined;~~

~~a piperidine group substituted by a tetrahydrofuranyl, tetrahydropyranyl or tetrahydrofuranylmethyl group;~~

~~a 6- to 7-membered alkyleneimino group optionally substituted by 1 or 2 C₁₋₂-alkyl groups wherein a methylene group in each case is replaced in the 4 position by an oxygen or sulfur atom, by an imino group substituted by the group R₆, or by a sulfinyl or sulfonyl group, whilst~~

~~R₆ denotes a hydrogen atom, a C₁₋₄-alkyl, 2-methoxy-ethyl, 3-methoxy-propyl, C₃₋₇-cycloalkyl, C₃₋₇-cycloalkyl-C₁₋₄-alkyl, tetrahydrofuran-3-yl, tetrahydropyran-3-yl, tetrahydropyran-4-yl, tetrahydrofuranylmethyl, formyl, C₁₋₄-alkylcarbonyl, C₁₋₄-alkylsulfonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl or di-(C₁₋₄-alkyl)-aminocarbonyl group;~~

~~an imidazolyl group optionally substituted by 1 to 3 methyl groups;~~

~~a C₅₋₇-cycloalkyl group wherein a methylene group is replaced by an oxygen or sulfur atom, by an imino group substituted by the group R₆, by a sulfinyl or sulfonyl group, whilst R₆ is as hereinbefore defined,~~

~~or D together with E denotes a hydrogen, fluorine or chlorine atom,~~

~~a C₁₋₄-alkyl group optionally substituted by 1 to 5 fluorine atoms,~~

~~a C₃₋₆-cycloalkyl group,~~

~~an aryl, heteroaryl, C₁₋₄-alkylcarbonyl or arylcarbonyl group,~~

~~a carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl or di-(C₁₋₄-alkyl)-aminocarbonyl group or~~

~~a carbonyl which is substituted by a 4 to 7 membered alkyleneimino group, whilst in the abovementioned 6 to 7 membered alkyleneimino groups in each case a methylene group may be replaced in the 4 position by an oxygen or sulfur atom, by an imino group substituted by the group R₆, by a sulfinyl or sulfonyl group, whilst R₆ is as hereinbefore defined, and~~

R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₆-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl, hydroxy, C₁₋₄-alkoxy, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, pyrrolidino, piperidino, morpholino, piperazino, N-(C₁₋₂-alkyl)-piperazino, hydroxy-C₁₋₂-alkyl, C₁₋₄-alkoxy-C₁₋₂-alkyl, amino-C₁₋₂-alkyl, C₁₋₄-alkylamino-C₁₋₂-alkyl, or di-(C₁₋₄-alkyl)-amino-C₁₋₂-alkyl, pyrrolidino-C₁₋₂-alkyl, piperidino-C₁₋₂-alkyl, morpholino-C₁₋₂-alkyl, piperazino-C₁₋₂-alkyl or N-(C₁₋₂-alkyl)-piperazino-C₁₋₂-alkyl group, whilst the abovementioned monosubstituted cycloalkyl moieties may additionally be substituted by a C₁₋₃-alkyl group,

~~a tetrahydrofuran 3-yloxy, tetrahydropyran 3-yloxy, tetrahydropyran 4-yloxy or tetrahydrofuranylmethoxy group,~~

~~an C₂₋₄-alkoxy group substituted in β , γ , or δ position with regard to the oxygen atom by an azetidin-1-yl, 4-methyl-homopiperazine or 4-ethyl-homopiperazine group;~~

~~a ~~3-pyrrolidinyl, 2-pyrrolidinyl-C₁₋₄-alkoxy, 3-pyrrolidinyl-C₁₋₄-alkoxy, 3-piperidinyl, 4-piperidinyl, 2-piperidinyl-C₁₋₄-alkoxy, 3-piperidinyl-C₁₋₄-alkoxy, 4-piperidinyl-C₁₋₄-alkoxy, 3-hexahydro-azepinyl, 4-hexahydro-azepinyl, 2-hexahydro-azepinyl-C₁₋₄-alkoxy, 3-hexahydro-azepinyl-C₁₋₄-alkoxy or 4-hexahydro-azepinyl-C₁₋₄-alkoxy~~ group wherein in each case the cyclic nitrogen atom is substituted by the group R₆, where R₆ is as hereinbefore defined, whilst~~

by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which in each case may be monosubstituted by R₇, mono-, di- or trisubstituted by R₈ or monosubstituted by R₇ and additionally mono- or disubstituted by R₈, wherein the substituents may be identical or different and

R₇ denotes a cyano, carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl, di-(C₁₋₄-alkyl)-aminocarbonyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, hydroxy, C₁₋₄-alkylsulfonyloxy, trifluoromethyloxy, nitro, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, C₁₋₄-alkylcarbonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylcarbonylamino, C₁₋₄-alkylsulfonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylsulfonylamino, aminosulfonyl, C₁₋₄-alkylaminosulfonyl or di-(C₁₋₄-alkyl)-aminosulfonyl group ~~or a carbonyl group which is substituted by a 5 to 7 membered alkyleneimino group, whilst in the abovementioned 6 to 7 membered alkyleneimino groups in each case a methylene group in the 4 position may be replaced by an oxygen or sulfur atom, by a sulfinyl, sulfonyl, imino or N-(C₁₋₄-alkyl) imino group, and~~

R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group or

two groups R₈, if they are bound to adjacent carbon atoms, together denote a C₃₋₅-alkylene, methylenedioxy or 1,3-butadien-1,4-ylene group,

~~and the heteroaryl groups mentioned in the definition of the abovementioned groups include a 5-membered heteroaromatic group which contains an imino group, an oxygen or sulfur atom or an imino group, an oxygen or sulfur atom and one or two nitrogen atoms, or~~

~~a 6-membered heteroaromatic group which contains one, two or three nitrogen atoms,~~

~~whilst the abovementioned 5-membered heteroaromatic groups may be substituted in each case by 1 or 2 methyl or ethyl groups and the abovementioned 6-membered heteroaromatic groups may be substituted in each case by 1 or 2 methyl or ethyl groups or by a fluorine, chlorine, bromine or iodine atom or by a trifluoromethyl, hydroxy, methoxy or ethoxy group,~~

~~or the tautomers, or stereoisomers and or pharmaceutically acceptable salts thereof.~~

2. (currently amended) ~~Bicyclic heterocycles~~ A quinazoline of general formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ to R₃, whilst

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C₁₋₄-alkyl, hydroxy, C₁₋₄-alkoxy, C₃₋₆-cycloalkyl, C₄₋₆-cycloalkoxy, C₂₋₅-alkenyl or C₂₋₅-alkynyl group,

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a methyl or methoxy group substituted by 1 to 3 fluorine atoms,

a cyano or nitro group and

R₃ denotes a hydrogen, fluorine, chlorine or bromine atom,

a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,

X denotes ~~a methine group substituted by a cyano group or a nitrogen atom,~~

A denotes an imino group,

B denotes a carbonyl ~~or sulfonyl~~ group,

C denotes a 1,3-allenylene, 1,1- or 1,2-vinylene group,

an ethynylene or 1,3-butadien-1,4-ylene group,

D denotes an alkylene, ~~CO-alkylene or SO₂-alkylene~~ group wherein the alkylene moiety in each case contains 1 to 4 carbon atoms and additionally 1 to 4 hydrogen atoms in the alkylene moiety may be replaced by fluorine atoms, ~~whilst the linking of the CO-alkylene or SO₂-alkylene group to the adjacent group C in each case must take place via the carbonyl or sulfonyl group,~~

~~a CO-O-alkylene, CO-NR₄-alkylene or SO₂-NR₄-alkylene group wherein the alkylene moiety in each case contains 1 to 4 carbon atoms, whilst the linking to the adjacent group C in each case must take place via the carbonyl or sulfonyl group, wherein~~

R₄ denotes a hydrogen atom or a C₁₋₄-alkyl group,

~~or, if D is bound to a carbon atom of the group E, it may also denote a bond,~~

~~or, if D is bound to a nitrogen atom of the group E, it may also denote a carbonyl or sulfonyl group,~~

E denotes a di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, where

R₅ denotes a hydroxy, C₁₋₄-alkoxy or di-(C₁₋₄-alkyl)-amino group,

~~a 4 to 7 membered alkyleneimino group optionally substituted by one or two methyl groups or~~

~~a 6 to 7 membered alkyleneimino group optionally substituted by one or two methyl groups wherein in each case a methylene group in position 4 is replaced by an oxygen or sulfur atom, or by a sulfinyl, sulfonyl or N-(C₁₋₄-alkyl) imino group,~~

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties in each case are substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, wherein the substituents may be identical or different and R₅ is as hereinbefore defined,

a C₃₋₇-cycloalkylamino or C₃₋₇-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom is substituted by a further C₁₋₄-alkyl group,

~~a C₁₋₄-alkylamino group wherein the nitrogen atom is substituted by a tetrahydrofuran-3-yl, tetrahydropyran-3-yl, tetrahydropyran-4-yl, tetrahydrofuranylmethyl, 1-(tetrahydrofuran-3-yl) piperidin-4-yl, 1-(tetrahydropyran-3-yl) piperidin-4-yl, 1-(tetrahydropyran-4-yl) piperidin-4-yl, N-(C₁₋₂-alkyl)-3-pyrrolidinyl, N-(C₁₋₂-alkyl)-3-piperidinyl, N-(C₁₋₂-alkyl)-4-piperidinyl, N-(C₁₋₂-alkyl)-3-hexahydro-azepinyl or N-(C₁₋₂-alkyl)-4-hexahydro-azepinyl group,~~

~~an 4 to 7 membered alkyleneimino group optionally substituted by 1 to 4 methyl groups, which may be substituted either at a cyclic carbon atom or at one of the methyl groups by the group R₅, where R₅ is as hereinbefore defined,~~

~~a piperidino group substituted by a tetrahydrofuranyl, tetrahydropyranyl or tetrahydrofuranylmethyl group,~~

~~a 6 to 7 membered alkyleneimino group optionally substituted by 1 or 2 methyl groups wherein in each case a methylene group is replaced in the 4 position by an oxygen or sulfur atom, by an imino group substituted by the group R₆, by a sulfinyl or sulfonyl group, whilst~~

~~R₆ denotes a C₁₋₄-alkyl, 2-methoxy-ethyl, 3-methoxy-propyl, C₃₋₇-cycloalkyl, C₃₋₇-cycloalkyl-C₁₋₄-alkyl, tetrahydrofuran-3-yl, tetrahydropyran-3-yl, tetrahydropyran-4-yl, tetrahydrofuranylmethyl, formyl, C₁₋₄-alkylcarbonyl, C₁₋₄-alkylsulfonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl or di-(C₁₋₄-alkyl)-aminocarbonyl group,~~

~~a C₃₋₇-cycloalkyl group wherein a methylene group is replaced by an oxygen or sulfur atom, by an imino group substituted by the group R₆, or by a sulfinyl or sulfonyl group, where R₆ is as hereinbefore defined,~~

~~or D together with E denotes a hydrogen, fluorine or chlorine atom,~~

~~a C₁₋₄-alkyl group optionally substituted by 1 to 5 fluorine atoms,~~

~~a C₃₋₆-cycloalkyl group,~~

~~an aryl, C₁₋₄-alkylcarbonyl or arylcarbonyl group,~~

~~a carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl or di-(C₁₋₄-alkyl)-aminocarbonyl group or~~

~~a carbonyl group which is substituted by a 4 to 7 membered alkyleneimino group, whilst in the abovementioned 6 to 7 membered alkyleneimino groups in each case a methylene group in the 4 position may be replaced by an oxygen or sulfur atom, by an imino group substituted by the group R₆, or by a sulfinyl or sulfonyl group, where R₆ is as hereinbefore defined, and~~

~~R₆ denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₆-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl, hydroxy, C₁₋₄-alkoxy, di-(C₁₋₄-alkyl)-amino, pyrrolidino, piperidino, morpholine, N-(C₁₋₂-alkyl)-piperazine, hydroxy-C₁₋₂-alkyl, C₁₋₄-alkoxy-C₁₋₂-alkyl, or di-(C₁₋₄-alkyl)-amino-C₁₋₂-alkyl, pyrrolidino-C₁₋₂-alkyl, piperidino-~~

~~C₁₋₂-alkyl, morpholino C₁₋₂-alkyl or N-(C₁₋₂-alkyl) piperazino C₁₋₂-alkyl group, whilst the abovementioned monosubstituted cycloalkyl moieties may additionally be substituted by a C₁₋₃-alkyl group,~~

~~a tetrahydrofuran 3-yloxy, tetrahydropyran 3-yloxy, tetrahydropyran 4-yloxy or tetrahydrofuranylmethoxy group,~~

~~an C₂₋₄-alkoxy group substituted in β , γ , or δ position with regard to the oxygen atom by an azetidin-1-yl, 4-methyl homopiperazino or 4-ethyl homopiperazino group,~~

~~a 3-pyrrolidinyl, 2-pyrrolidinyl C₁₋₄-alkyloxy, 3-pyrrolidinyl C₁₋₄-alkyloxy, 3-piperidinyl, 4-piperidinyl, 2-piperidinyl C₁₋₄-alkyloxy, 3-piperidinyl C₁₋₄-alkyloxy, 4-piperidinyl C₁₋₄-alkyloxy, 3-hexahydro-azepinyl, 4-hexahydro-azepinyl, 2-hexahydro-azepinyl C₁₋₄-alkyloxy, 3-hexahydro-azepinyl C₁₋₄-alkyloxy or 4-hexahydro-azepinyl C₁₋₄-alkyloxy group wherein in each case the cyclic nitrogen atom is substituted by the group R₆, where R₆ is as hereinbefore defined, whilst~~

by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which may in each case be monosubstituted by R₇, mono-, di- or trisubstituted by R₈ or monosubstituted by R₇ and additionally mono- or disubstituted by R₈, wherein the substituents may be identical or different and

R₇ denotes a cyano, carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl, di-(C₁₋₄-alkyl)-aminocarbonyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, hydroxy, C₁₋₄-alkylsulfonyloxy, trifluoromethyloxy, nitro, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, C₁₋₄-alkylcarbonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylcarbonylamino, C₁₋₄-alkylsulfonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylsulfonylamino, aminosulfonyl, C₁₋₄-alkylaminosulfonyl or di-(C₁₋₄-alkyl)-aminosulfonyl group or a carbonyl group which is substituted by a 5- to 7-membered alkyleneimino group, whilst in the abovementioned 6- to 7-membered alkyleneimino groups in each case a methylene group may be replaced in the 4 position by an oxygen or sulfur atom, by a sulfinyl, sulfonyl, imino or N-(C₁₋₄-alkyl)-imino group, and

R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group or

two groups R₈, if they are bound to adjacent carbon atoms, together denote a C₃₋₅-alkylene, methylenedioxy or 1,3-butadien-1,4-ylene group,

or the tautomers, or stereoisomers and or pharmaceutically acceptable salts thereof.

3. (currently amended) ~~Bicyclic heterocycles~~ A quinazoline of ~~general~~ formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ and R₂, where

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine or bromine atom,

a methyl, trifluoromethyl or methoxy group,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a 1,2-vinylene group,

an ethynylene or 1,3-butadien-1,4-ylene group,

D denotes a C₁₋₄-alkylene group,

~~or, if D is bound to a carbon atom of the group E, it may also denote a bond,~~

~~or, if D is bound to a nitrogen atom of the group E, it may also denote a carbonyl group,~~

E denotes a di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst

R₅ denotes a hydroxy, C₁₋₃-alkoxy or di-(C₁₋₃-alkyl)-amino group,

~~a pyrrolidino, piperidino or morpholino group,~~

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties in each case are substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, wherein the substituents may be identical or different and R₅ is as hereinbefore defined,

~~an C₁₋₄-alkylamino group substituted at the nitrogen atom by a tetrahydrofuran-3-yl, tetrahydropyran-3-yl, tetrahydropyran-4-yl, tetrahydrofuranylmethyl, 1-(C₁₋₂-alkyl)-pyrrolidin-3-yl, 1-(C₁₋₂-alkyl)-piperidin-3-yl, 1-(C₁₋₂-alkyl)-piperidin-4-yl, 1-(tetrahydrofuran-3-yl)-piperidin-4-yl, 1-(tetrahydropyran-3-yl)-piperidin-4-yl or 1-(tetrahydropyran-4-yl)-piperidin-4-yl group,~~

a C₃₋₅-cycloalkylamino or C₃₋₅-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom is substituted by a further C₁₋₃-alkyl group,

~~a 5 to 7 membered alkyleneimino group optionally substituted by 1 or 2 methyl groups which may be substituted either at a cyclic carbon atom or at one or the methyl groups by the group R₅, where R₅ is as hereinbefore defined, or~~

~~a piperidino group substituted by a tetrahydrofuranyl, tetrahydropyranyl or tetrahydrofuranylmethyl group;~~

~~a piperidino group optionally substituted by 1 or 2 methyl groups wherein the methylene group is replaced in the 4 position by an oxygen or sulfur atom, by sulfinyl or sulfonyl group or by an imino group substituted by the group R₆, whilst~~

~~R₆ denotes a C₁₋₃-alkyl, 2-methoxy-ethyl, 3-methoxy-propyl, C₂₋₆-cycloalkyl, C₂₋₆-cycloalkyl-C₁₋₃-alkyl, tetrahydrofuran-3-yl, tetrahydropyran-3-yl, tetrahydropyran-4-yl, tetrahydrofuranylmethyl, C₁₋₃-alkylcarbonyl, C₁₋₃-alkylsulfonyl, aminocarbonyl, C₁₋₃-alkylaminocarbonyl or di-(C₁₋₃-alkyl)-aminocarbonyl group;~~

~~or D together with E denotes a hydrogen atom;~~

~~a C₁₋₃-alkyl group;~~

~~an aryl or C₁₋₄-alkylcarbonyl group or~~

~~a C₁₋₄-alkoxy carbonyl group;~~

~~R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₄-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl or C₁₋₃-alkoxy group,~~

~~a tetrahydrofuran-3-yloxy, tetrahydropyran-3-yloxy, tetrahydropyran-4-yloxy or tetrahydrofuranylmethoxy group;~~

~~an C₂₋₄-alkoxy group substituted in β , γ , or δ position with regard to the oxygen atom by an azetidin-1-yl, 4-methyl-homopiperazino or 4-ethyl-homopiperazino group;~~

~~a 3-pyrrolidinyl, 2-pyrrolidinyl C₁₋₃-alkyloxy, 3-pyrrolidinyl C₁₋₃-alkyloxy, 3-piperidinyl, 4-piperidinyl, 2-piperidinyl C₁₋₃-alkyloxy, 3-piperidinyl C₁₋₃-alkyloxy, 4-piperidinyl C₁₋₃-alkyloxy, 3-hexahydro-azepinyl, 4-hexahydro-azepinyl, 2-hexahydro-azepinyl C₁₋₃-alkyloxy, 3-hexahydro-azepinyl C₁₋₃-alkyloxy or 4-hexahydro-~~

~~azepinyl C₁₋₃-alkyloxy group wherein in each case the cyclic nitrogen atom is substituted by a methyl or ethyl group, whilst~~

~~by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which may be mono-, di- or trisubstituted by R₈, wherein the substituents may be identical or different and~~

~~R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,~~

~~or the tautomers, or stereoisomers and or pharmaceutically acceptable salts thereof.~~

4. (currently amended) ~~Bicyclic heterocycles~~ A quinazoline of general formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group, whilst the phenyl nucleus is substituted in each case by the radicals R₁ and R₂, whilst

R₁ and R₂, which may be identical or different, each denotes a hydrogen, fluorine, chlorine or bromine atom,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a 1,2-vinylene, ~~ethinylene~~ ethynylene or 1,3-butadien-1,4-ylene group,

D denotes an C₁₋₃-alkylene group,

E denotes a Di-(C₁₋₄-alkyl)-amino group, wherein the alkyl moieties may be identical or different,

a methylamino or ethylamino group each substituted at the nitrogen atom by a 2-methoxyethyl, 1-methoxy-2-propyl, 2-methoxypropyl, 3-methoxypropyl, tetrahydrofuran-3-yl, tetrahydropyran-4-yl, tetrahydrofuran-2-ylmethyl, 1-methylpiperidin-4-yl, 1-ethylpiperidin-4-yl, 1-(tetrahydrofuran-3-yl)-piperidin-4-yl, cyclopropyl or cyclopropylmethyl group,

a ~~Bis~~bis-(2-methoxyethyl)amino group,

~~a pyrrolidino, piperidino or morpholino group each optionally substituted by one or two methyl groups,~~

~~a piperazino group substituted in 4 position by a methyl, ethyl, cyclopropyl, cyclopropylmethyl, 2-methoxyethyl, tetrahydrofuran-3-yl, tetrahydropyran-4-yl or tetrahydrofuran-2-ylmethyl group,~~

~~a thiomorpholino, S-oxidethiomorpholino or S,S-dioxidethiomorpholino group,~~

~~a 2-(methoxymethyl)pyrrolidino, 2-(ethoxymethyl)pyrrolidino, 4-hydroxypiperidino, 4-methoxypiperidino, 4-ethoxypiperidino, 4-(tetrahydrofuran-3-yl)piperidino or 4-morpholinopiperidino group~~

~~or D together with E denote a hydrogen atom, a methyl, phenyl, methoxycarbonyl or ethoxycarbonyl group and~~

R_c denotes a cyclopropylmethoxy, cyclobutylmethoxy, cyclopentylmethoxy or cyclohexylmethoxy group,

a cyclobutyloxy, cyclopentyloxy or cyclohexyloxy group,

~~a tetrahydrofuran-3-yloxy, tetrahydropyran-4-yloxy or tetrahydrofuran-2-ylmethoxy group,~~

~~a straight chained C₂₋₄-alkoxy group terminally substituted by an azetidin-1-yl, 4-methyl-homopiperazino or 4-ethyl-homopiperazino group;~~

~~a 1-methyl-piperidin-4-yloxy or 1-ethyl-piperidin-4-yloxy group;~~

~~a (1-methyl-piperidin-4-yl)-C₁₋₃-alkyloxy or (1-ethyl-piperidin-4-yl)-C₁₋₃-alkyloxy group;~~

or the tautomers, or stereoisomers and or pharmaceutically acceptable salts thereof.

5. (currently amended) ~~Bicyclic heterocycles~~ A quinazoline of general formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a 1-phenylethyl group or a phenyl group wherein the phenyl nucleus is substituted by the radicals R₁ and R₂, whilst

R₁ and R₂, which may be identical or different, each denote a hydrogen, fluorine, chlorine or bromine atom,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a 1,2-vinylene, ~~ethynylene~~ ethynylene or 1,3-butadien-1,4-ylene group,

D denotes a methylene group,

E denotes a dimethylamino, diethylamino, Bis(2-methoxyethyl)amino, *N*-methyl-*N*-(2-methoxyethyl)amino, *N*-ethyl-*N*-(2-methoxyethyl)amino, *N*-methyl-*N*-cyclopropylamino, *N*-methyl-*N*-cyclopropylmethyl-amino, *N*-methyl-*N*-(1-methoxy-2-propyl)amino, *N*-methyl-

~~*N*-(2-methoxypropyl)amino, or *N*-methyl-*N*-(3-methoxypropyl)amino, *N*-methyl-*N*-(tetrahydrofuran-3-yl)amino, *N*-methyl-*N*-(tetrahydropyran-4-yl)amino, *N*-methyl-*N*-(tetrahydrofuran-2-ylmethyl)amino or *N*-methyl-*N*-(1-methylpiperidin-4-yl)amino group,~~

~~a pyrrolidino, piperidino or morpholino group each optionally substituted by one or two methyl groups,~~

~~a piperazino group substituted in 4 position by a methyl, ethyl, cyclopropylmethyl or 2-methoxyethyl group,~~

~~a S-oxidithiomorpholino group,~~

~~a 2-(methoxymethyl)pyrrolidino, 4-hydroxypiperidino or 4-methoxypiperidino group~~

~~or D together with E denote a hydrogen atom, a methyl, phenyl or ethoxycarbonyl group, and~~

~~R_c denotes a cyclopropylmethoxy, cyclobutyloxy or cyclopentyloxy group,~~

~~a tetrahydrofuran-3-yloxy, tetrahydropyran-4-yloxy or tetrahydrofuran-2-ylmethoxy group,~~

~~a straight chained C₂₋₄-alkoxy group terminally substituted by an azetidin-1-yl or 4-methylhomopiperazino group,~~

~~a 1-methyl-piperidin-4-yloxy group or~~

~~a (1-methylpiperidin-4-yl)-C₁₋₃-alkyloxy group,~~

~~or the tautomers, or stereoisomers and or pharmaceutically acceptable salts thereof.~~

6. (currently amended) The following compounds of general formula I according to claim 1:

(a) 4-[(3-Chloro-4-fluorophenyl)amino]-7-[3-(1-methylpiperidin-4-yl)propyloxy]-6-[(vinylcarbonyl)amino]quinazoline;

~~(b) 4-[(3-Chloro-4-fluorophenyl)amino]-6-[[4-(N,N-diethylamino)-1-oxo-2-buten-1-yl]amino]-7-cyclopropylmethoxyquinazoline and~~

~~(c) 4-[(3-Chloro-4-fluorophenyl)amino]-6-[[4-(morpholin-4-yl)-1-oxo-2-buten-1-yl]amino]-7-cyclopropylmethoxyquinazoline~~

as well as the salts thereof or pharmaceutically acceptable salts thereof.

7. (currently amended) Physiologically-Pharmaceutically acceptable salts of the compounds according to ~~at least one of claims 1 to 6~~ with inorganic or organic acids or bases.

8. (currently amended) Pharmaceutical compositions containing a compound according to at least one of claims 1 to 6, ~~or a physiologically acceptable salt according to claim 7~~ optionally together with one or more inert carriers and/or diluents.

9. (currently amended) ~~Use of a compound according to at least one of claims 1 to 7 for preparing a pharmaceutical composition which is suitable for treating~~ A method for treating or preventing a disease comprising administering a pharmaceutical composition according to one of claims 1 to 6, wherein said disease is selected from the group consisting of: benign or malignant tumors, for preventing and treating diseases of the airways and lungs and for treating diseases of the gastrointestinal tract and the bile duct and gall bladder.

Claims 10-11 (canceled)

12. (new) Pharmaceutical compositions containing a physiologically acceptable salt according to claim 7, optionally together with one or more inert carriers and/or diluents.

13. (new) A method for treating or preventing a disease comprising administering a pharmaceutical composition according to claim 7, wherein said disease is selected from the group consisting of: benign or malignant tumors, diseases of the airways and lungs and diseases of the gastrointestinal tract and the bile duct and gall bladder.

REMARKS

Claims 1-9, 12 and 13 are currently pending in the instant application. Claims 1-9 have been amended. Claim 8 has been amended to correct dependency on multiple claim 7. New claim 12 contains the deleted subject matter of claim 8. Claim 9 has been amended to correct dependency on multiple claim 7. New claim 13 contains the deleted subject matter of claim 9. Claims 10 and 11 have been canceled.

No new matter has been added. In light of the above amendments, claims 1-9, 12 and 13 are under active consideration in this application.

Priority

The instant application is the national stage of International Application PCT/EP00/05547 (WO 00/78735) filed on June 16, 2000 which claims benefit to prior U.S. Provisional Application 60/146,644, filed July 30, 1999 and prior German Application Nos. DE 199 28 281 and DE 100 23 085, filed June 21, 1999 and May 11, 2000, respectively. Benefit of the earlier filing date of the prior International Application was claimed pursuant to 35 U.S.C. §365(c) on the Declaration for Utility or Design Application, filed on April 25, 2002 in three counterparts, copies of which are submitted herewith. Benefit of the earlier filing date of the prior International Application was incorrectly claimed under 371 on the Application Data Sheet. A new Application Data Sheet is submitted herewith. Attorney for Applicants submits that the priority is in order and respectfully requests acknowledgement.

Specification

The specification is objected to for informalities regarding the continuity information. The specification has been amended to recite:

This application is a continuation of International Application PCT/EP00/05547 (WO 00/78735) filed on June 16, 2000 which claims benefit to prior U.S. Provisional Application 60/146,644, filed July 30, 1999 and prior German Application Nos. DE 199 28 281 and DE 100 23 085, filed June 21, 1999 and May 11, 2000, respectively. Benefit of the earlier filing date of the prior International Application is hereby claimed pursuant to 35 U.S.C. § 365(c).

This objection, therefore, has been obviated.

Claim Objections

Claims 8-11 are objected to as being in improper form for dependency on multiple dependent claim 7. Claims 10 and 11 have been cancelled without prejudice. Claims 8 and 9 have been amended to depend only on claims 1 to 6, thus this objection has been obviated.

Rejections under Section 112

Claims 1-7 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. According to the Examiner, claims 1-5 are indefinite in the recitation "Bicyclic heterocycles of general Formula". Applicants disagree, however, in order to advance prosecution, claims 1-5 have been amended according to the Examiner's suggestion to recite "A quinazoline compound of Formula". This rejection, therefore, has been overcome.

According to the Examiner, claims 1-5 are indefinite in the recitation "the tautomers, stereoisomers and salts thereof". Applicants disagree, however, in order to advance prosecution, claims 1-5 have been amended according to the Examiner's suggestion to recite "or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof". This rejection, therefore, has been overcome.

According to the Examiner, claim 6 is indefinite in the recitation "as well as the salts thereof". Applicants disagree, however, in order to advance prosecution, claim 6 has been amended according to the Examiner's suggestion to recite "or pharmaceutically acceptable salts thereof". This rejection, therefore, has been overcome.

According to the Examiner, claim 7 is indefinite in the recitation "Physiologically acceptable salts of the compounds...to at least one of claims...". Applicants disagree, however, in order to advance prosecution, claim 7 has been amended according to the Examiner's suggestion to recite "Pharmaceutically acceptable salts of the compounds...to one of claims...". This rejection, therefore, has been overcome.

Rejections under Section 103

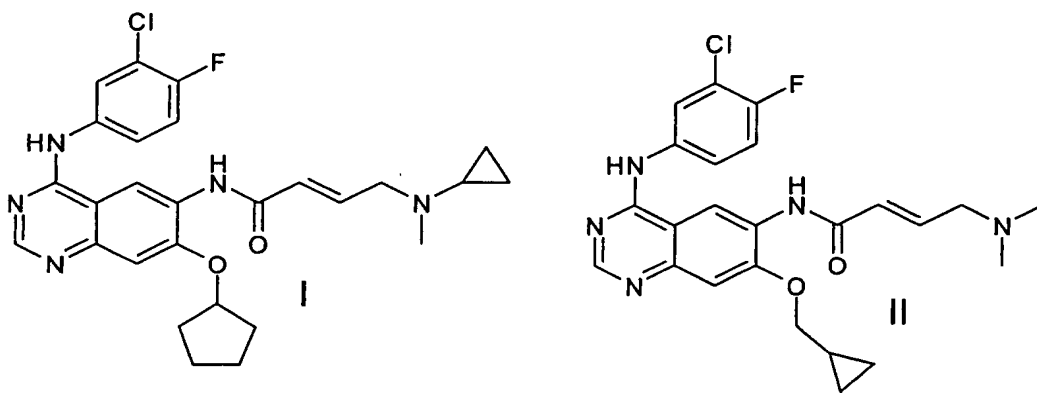
Claims 1-7 are rejected under 36 U.S.C. §103(A) as being obvious in view of Barker, EP 566226 ("the '226 reference") and further in view of Bridges *et al.*, WO 9738983 ("the '983 reference").

According to the Examiner, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the '226 reference, *i.e.*, substituted quinazoline with free 6-NH₂ and condense with maleic anhydride to get -NHCO-CH=CH-COOH, and to modify the end group as taught by the '983 reference.

Applicants respectfully disagree. The claims, as amended, refer only to quinazolines which are substituted in position 7 (which is R_c) with cycloalkyloxy- or cycloalkylalkoxy-groups.

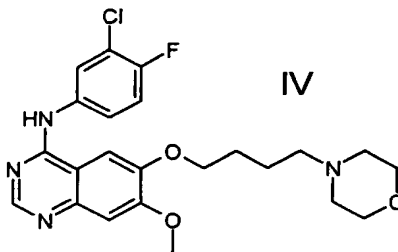
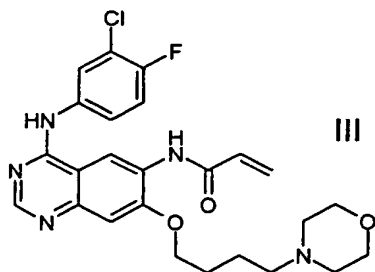
The difference of the compounds as claimed to the compounds of the '226 reference and the '983 reference cited by the Examiner is that the compounds of the present invention, in contrast to the cited state of the art, comprise only cycloalkyloxy- or cycloalkylalkoxy-groups at position 7.

Furthermore, these groups are responsible for a higher stability with regard to microsomal metabolic degradation. The half-lives of two of the compounds falling under the scope of the amended claims was evaluated in human liver microsomes. These compounds have the following formula:



The $t_{1/2}$ -value of compound I was 30 min and for compound II it was 107 min.

Further, two compounds falling under the scope of the cited applications having the following formula were evaluated:



The $t_{1/2}$ -value for compound III was 10 min and for compound IV it was 18 min.

In contrast to the compounds of the cited state of the art, the compounds of the present invention, having a cycloalkyloxy- or cycloalkylmethoxy-group as R_c , are much more stable with regard to microsomal metabolic degradation. This advantage cannot be derived from the cited documents. Therefore, the amended claims are not obvious in view of the prior art. This rejection under Section 103, therefore, should be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that all of the objections and rejections have been overcome and must be withdrawn. Further, Applicants submit that the application is now in form for issuance and an early allowance is earnestly requested. If any issues remain, the Examiner is invited to telephone the Attorney at the number below.

Respectfully submitted,

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January 8, 2004

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)	Attorney Docket Number	5/1262
	First Named Inventor	Frank Himmelsbach
	COMPLETE IF KNOWN	
	Application Number	10 / 016,280
	Filing Date	December 10, 2001
	Group Art Unit	
<input type="checkbox"/> Declaration Submitted with Initial Filing	OR	<input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)
Examiner Name		

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BICYCLIC HETEROCYCLES, PHARMACEUTICAL COMPOSITIONS CONTAINING THESE COMPOUNDS, THEIR USE AND PROCESSES FOR PREPARING THEM

the specification of which
☐ is attached hereto
OR
☒ was filed on (MM/DD/YYYY) **12/10/2001** as United States Application Number or PCT International Application Number **10/016,280** and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
100 23 085.7	DE	05/11/2000	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
199 28 281.1	DE	06/21/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)
60/146,644	07/30/1999

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/EP00/05547	06/21/1999	

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As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

☐ Customer Number 28505 →

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Number Bar Code
Label here

☒ OR Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Robert P. Raymond	25,089	Susan K. Pocchiarri	45,016
Alan R. Stempel	28,991	Philip I. Datlow	41,482
Mary-Ellen M. Devlin	27,928	Timothy X. Witkowski	40,232
Anthony P. Bottino	41,629		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number 28505 OR ☐ Correspondence address below

Name			
Address			
Address			
City	State	ZIP	
Country	Telephone	Fax	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: FRANK HIMMELSBACH ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])		Family Name or Surname	
Frank		HIMMELSBACH	
Inventor's Signature			Date
Residence: City	Mittelbiberach	State	Country
			Germany
Post Office Address	Ahornweg 16		
Post Office Address			
City	Mittelbiberach	State	Country
			Germany

☒ Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

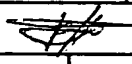
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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page <u>1</u> of <u>2</u>
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Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Elke				LANGKOPF			
Inventor's Signature						Date	
Residence: City	Warthausen	State		Country	Germany	Citizenship	DE
Post Office Address	Schloss 3						
Post Office Address							
City	Warthausen	State		ZIP	88447	Country	Germany
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Thomas				METZ			
Inventor's Signature						Date	
Residence: City	Wien	State		Country	Austria	Citizenship	DE
Post Office Address	Traungasse 6/5						
Post Office Address							
City	Wien	State		ZIP	1030	Country	Austria
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Flavio				SOLCA			
Inventor's Signature						Date	26.02.2002
Residence: City	Wien	State		Country	Austria	Citizenship	CH
Post Office Address	Fimbingergasse 1/9						
Post Office Address							
City	Wien	State		ZIP	1230	Country	Austria

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Case No. 5/1262

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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page <u>2</u> of <u>2</u>
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Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Birgit				JUNG			
Inventor's Signature						Date	
Residence: City	Schwabenheim	State		Country	Germany	Citizenship	DE
Post Office Address	Muehlstrasse 23						
Post Office Address							
City	Schwabenheim	State		ZIP	55270	Country	Germany
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Anke				BAUM			
Inventor's Signature	<i>A. Baum</i>					Date	26.02.02
Residence: City	Alland	State		Country	Austria	Citizenship	DE
Post Office Address	Groisbach 13						
Post Office Address							
City	Alland	State		ZIP	2534	Country	Austria
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	

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	Filing Date	December 10, 2001
	Group Art Unit	
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the specification of which (Title of the Invention)

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199 28 281.1	DE	06/21/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Application Number(s)	Filing Date (MM/DD/YYYY)
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PCT/EP00/05547	06/21/1999	

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As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

☐ Customer Number 28505

OR

☒ Registered practitioner(s) name/registration number listed below

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Number Bar Code
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Name	Registration Number	Name	Registration Number
Robert P. Raymond	25,089	Susan K. Pocchiari	45,016
Alan R. Stempel	28,991	Philip I. Datlow	41,482
Mary-Ellen M. Devlin	27,928	Timothy X. Witkowski	40,232
Anthony P. Bottino	41,629		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 28505 OR ☐ Correspondence address below

Name				
Address				
Address				
City		State	ZIP	
Country	Telephone	Fax		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Frank	HIMMELSBACH

Inventor's Signature				Date	01/30/02
Residence: City	Mittelbiberach	State		Country	Germany
Post Office Address	Ahornweg 16				
Post Office Address					
City	Mittelbiberach	State		ZIP	88441
				Country	Germany

☒ Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Elke				LANGKOPF			
Inventor's Signature				Date	11/30/02		
Residence: City	Warthausen	State		Country	Germany	Citizenship	DE
Post Office Address	Schloss 3						
Post Office Address							
City	Warthausen	State		ZIP	88447	Country	Germany
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Thomas				METZ			
Inventor's Signature				Date			
Residence: City	Wien	State		Country	Austria	Citizenship	DE
Post Office Address	Traungasse 6/5						
Post Office Address							
City	Wien	State		ZIP	1030	Country	Austria
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Flavio				SOLCA			
Inventor's Signature				Date			
Residence: City	Wien	State		Country	Austria	Citizenship	CH
Post Office Address	Fimbingergasse 1/9						
Post Office Address							
City	Wien	State		ZIP	1230	Country	Austria

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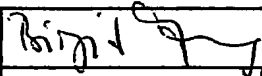
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Given Name (first and middle [if any])				Family Name or Surname			
Birgit				JUNG			
Inventor's Signature						Date	Feb 19/02
Residence: City	Schwabenheim	State		Country	Germany	Citizenship	DE
Post Office Address: Muehlstrasse 23							
Post Office Address:							
City	Schwabenheim	State		ZIP	55270	Country	Germany
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Anke				BAUM			
Inventor's Signature						Date	
Residence: City	Alland	State		Country	Austria	Citizenship	DE
Post Office Address: Groisbach 13							
Post Office Address:							
City	Alland	State		ZIP	2534	Country	Austria
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor					
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address:							
Post Office Address:							
City		State		ZIP		Country	

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Address			
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])		Family Name or Surname	
Frank		HIMMELSBACH	
Inventor's Signature	Date		
Residence: City	Mittelbiberach	State	Country Germany Citizenship DE
Post Office Address	Ahornweg 16		
Post Office Address			
City	Mittelbiberach	State	ZIP 88441 Country Germany

☒ Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

COPY

Please type a plus sign (+) inside this box → +

PTO/SB/02A (3-97)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page <u>1</u> of <u>2</u>
--------------------	---

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Elke				LANGKOPF			
Inventor's Signature						Date	
Residence: City	Warthausen	State		Country	Germany	Citizenship	DE
Post Office Address	Schloss 3						
Post Office Address							
City	Warthausen	State		ZIP	88447	Country	Germany
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Thomas				METZ			
Inventor's Signature	<i>Thomas Metz</i>					Date	01-28-02
Residence: City	Wien	State		Country	Austria	Citizenship	DE
Post Office Address	Traungasse 6/5						
Post Office Address							
City	Wien	State		ZIP	1030	Country	Austria
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Flavio				SOLCA			
Inventor's Signature						Date	
Residence: City	Wien	State		Country	Austria	Citizenship	CH
Post Office Address	Fimbingergasse 1/9						
Post Office Address							
City	Wien	State		ZIP	1230	Country	Austria

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Case No. 5/1262

COPY

Please type a plus sign (+) inside this box → +

PTO/SB/02A (3-97)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

+

<h2>DECLARATION</h2>	ADDITIONAL INVENTOR(S) Supplemental Sheet Page <u>2</u> of <u>2</u>
----------------------	---

Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Birgit				JUNG			
Inventor's Signature						Date	
Residence: City	Schwabenheim	State		Country	Germany	Citizenship	DE
Post Office Address	Muehlstrasse 23						
Post Office Address							
City	Schwabenheim	State		ZIP	55270	Country	Germany
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Anke				BAUM			
Inventor's Signature						Date	
Residence: City	Alland	State		Country	Austria	Citizenship	DE
Post Office Address	Groisbach 13						
Post Office Address							
City	Alland	State		ZIP	2534	Country	Austria
Name of Additional Joint Inventor, if any:				<input type="checkbox"/> A petition has been filed for this unsigned inventor			
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						Date	
Residence: City		State		Country		Citizenship	
Post Office Address							
Post Office Address							
City		State		ZIP		Country	

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Case No.

+



APPLICATION DATA SHEET

APPLICATION INFORMATION

Application Type::	Regular
Subject Matter::	Utility
CD-ROM or CD-R?::	None
Number of CD disks::	0
Number of copies of CDs::	0
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Number of copies of CRF::	0
Title::	Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them
Attorney Docket Number::	5/1262
Request for Early Publication?::	No
Request for Non-Publication?::	No
Total Drawing Sheets::	0
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

APPLICANT INFORMATION

Applicant Authority Type::	Inventor
Primary Citizenship Country::	Germany
Status::	Full Capacity
Given Name::	Frank
Family Name::	HIMMELSBACH
City of Residence::	Mittelbiberach
Country of Residence::	Germany
Street of mailing address::	Ahornweg 16
City of mailing address::	Mittelbiberach
Country of mailing address::	Germany

Postal or Zip Code of mailing address:: 88441

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Germany
Status:: Full Capacity
Given Name:: Elke
Family Name:: LANGKOPF
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Country of Residence:: Germany
Street of mailing address:: Schloss 3
City of mailing address:: Warthausen
Country of mailing address:: Germany
Postal or Zip Code of mailing address:: 88447

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Austria
Status:: Full Capacity
Given Name:: Thomas
Family Name:: METZ
City of Residence:: Wien
Country of Residence:: Austria
Street of mailing address:: Traungasse 6/5
City of mailing address:: Wien
Country of mailing address:: Austria
Postal or Zip Code of mailing address:: A-1030

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Switzerland
Status:: Full Capacity
Given Name:: Flavio
Family Name:: SOLCA
City of Residence:: Wien
Country of Residence:: Austria

Street of mailing address:: Fimbingergasse 1/9
City of mailing address:: Wien
Country of mailing address:: Austria
Postal or Zip Code of mailing address:: A-1230

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Germany
Status:: Full Capacity
Given Name:: Birgit
Family Name:: JUNG
City of Residence:: Schwabenheim
Country of Residence:: Germany
Street of mailing address:: Muehlstrasse 23
City of mailing address:: Schwabenheim
Country of mailing address:: Germany
Postal or Zip Code of mailing address:: 55270

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Austria
Status:: Full Capacity
Given Name:: Anke
Family Name:: BAUM
City of Residence:: Wien
Country of Residence:: Austria
Street of mailing address:: Herminengasse 10/12
City of mailing address:: Wien
Country of mailing address:: Austria
Postal or Zip Code of mailing address:: A-1020

CORRESPONDENCE INFORMATION

Correspondence Customer Number:: 28505

REPRESENTATIVE INFORMATION

Representative Customer Number:: 28505

DOMESTIC PRIORITY INFORMATION

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National Stage of	PCT/EP00/05547	06/21/1999
	Non-Provisional of	60/146,644	07/30/1999

FOREIGN PRIORITY INFORMATION

Country::	Application Number::	Filing Date::	Priority Claimed::
DE	199 28 281.1	06/21/1999	Yes
DE	100 23 085.7	05/11/2000	Yes

ASSIGNEE INFORMATION

Assignee name:: Boehringer Ingelheim Pharma KG
Street of mailing address:: Binger Strasse 173
City of mailing address:: Ingelheim
Country of mailing address:: Germany
Postal or Zip Code of mailing address:: 55216



UNITED STATES PATENT AND TRADEMARK OFFICE

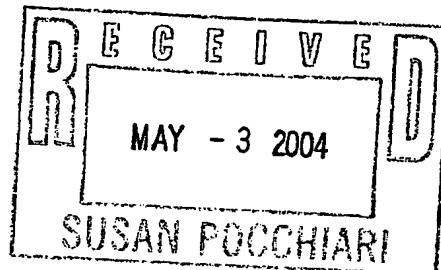
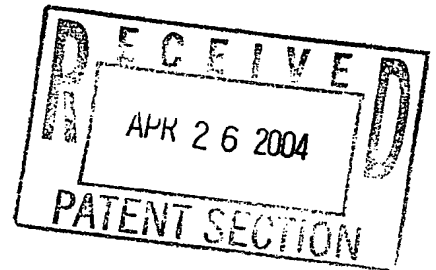
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351
28505	7590	04/23/2004		
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877				
			EXAMINER	
			PATEL, SUDHAKER B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/23/2004

7-23-04
10-23-04 LAST DAY

Please find below and/or attached an Office communication concerning this application or proceeding.





Office Action Summary

Application No.

10/016,280

Applicant(s)

HIMMELSBACH ET AL

Examiner

Sudhaker B. Patel, D.Sc.Tech.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 4/20/04.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' communication paper dated 1/8/04 is acknowledged.

Applicants have, cancelled claims 10-11, amended claims 1-9, and presented new claims 12,13. Therefore, the claims in this application are the claims 1-9,12,13.

Applicants' above stated amendments to claims, cancellation of claims together with their arguments and remarks have been reviewed, but not found persuasive for the allowance of this case as is for the reasons stated below. See interview summary dated 4/20/04 enclosed with this communication.

Election/Restrictions

2. Applicants have elected species of generic Formula (I) of claim 1, namely, compound of Example 3 recited in page 44 lines 20-22 (= 4-[(3-Chloro-4-fluorophenyl) amino]-6-[[4-(N, N-diethyl amino)-oxo-2-buten-1-yl] amino]-7-cyclopropylmethoxyquinazoline), claims (in part) 1-11, drawn to compounds, compositions, method of use, and the first recited process of making the same for the generic Formula (I). The restriction/election has been made FINAL in earlier Office communication paper dated 7/8/03.

Rejections maintained:

3. Applicants' above stated arguments, remarks and amendments have been reconsidered but not found persuasive for withdrawal of rejections made under 35 U.S.C.112 paragraph second for claims 1-5,7,8,9,12,13 for reasons already stated in prior Office communication paper dated 7/8/03. Following additional reasons apply.

(A). Claim 1 recites C variable as: "1,3-allenylene, 1,1- or 1,2-vinylene". It is not very clear as to what applicants want to present with. Ally group consists of 3 carbon atoms with 1 double bond. Alternatively it is a propylene group with 1 double bond. Similarly, vinyl group consists of 2 carbon atoms with 1 double bond". Correction to what is exactly and definitely claimed group(s) is required.

(B). Claims 1,3 recites C variable as: "1,3-butadien-1, 4-ylene". 1,3-butadien is having a core: "CH₂=CH-CH=CH₂ wherein the double bonds are carbon atoms 1 and 3 respectively". Are diacetylene(s) with 4 carbon atoms excluded or a mixture of a double bond and a triple bond in a 4-carbon chain/bridge? Correction to exact and definite structure is required.

©. Claims 1,3 recite C components as: "ethynylene group". Is acetylene group excluded?. Correction to exact and definite structure is required.

(D). Claims 9,13 recite: "or preventing". Cancellation is required.

(E). Claim 12 recites: "with one or more inert carriers and/or diluents". A pharmaceutical composition with a carrier is different from with a carrier and a diluent. With other combination(s) either alone or in plurals the nature and composition(s) are

Art Unit: 1624

also different. Correction to: "with an inert carrier and with or without a diluent" is required.

(F). Claims 9, 13 recite "benign or malignant tumors". Correction to a single, specific and definite tumor that can be treated by the invention is required.

(G). Claims 1-9, are presented after amendments to delete prior art(s), but based on above stated reasons it is difficult to read what is exactly claimed. E.g. The reference Wissner et al (WO 9909016, also cited as Chemical Abstract DN 130:196664).

Claims 2,4,5,7,8 are rejected because they are dependent on the rejected claim(s).

Priority

4. This application claims benefit of 60146644 filed 7/30/1999. It also claims the priority to foreign applications (1). Germany 19928281.1 filed 6/21/1999. (2). Germany 10023085.7 5/11/200. On going thru' the records and the eDAN electronic file as received by the Examiner, this file is missing the certified true copies of both of the foreign files stated above. Applicants are urged to provide the same to complete the records of e-DAN system prior to allowance. See interview summary attached with this communication.

Specification

5. The specification is amended as per applicants page 2 of the amendment dated 1/1/8/04.

Conclusion

Allowable Subject Matter

6. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 1-5,7-9,12,13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and others together with other requirements, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. The closest prior Art(s) of record reference. '226(EP566226) is teaching making of quinazoline tyrosine kinase-inhibiting anticancer agents.

The ref. '226 chemical core is:

"4,6-Quinazolinediamine, 7-methoxy-N-4-(3methylphenyl)"

The ref. '226 differs from the instant claims by having CH₃-O- instead of -O-CH₂-Cyclocllyl, and -NH₂ instead of -NH-CO-CH=CH-CH₂-N(alkyl)₂.

The other ref. '983(WO 9738983) teaches making of irreversible inhibitors of tyrosine kinase. See compound of Example 55 on page 123, and the compounds of claim 1 on pages 152-154.

Art Unit: 1624

The references either alone or in combination do not suggest totarrive at the instant claims as presented after amendments and cancellation of claims 10,11 .

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

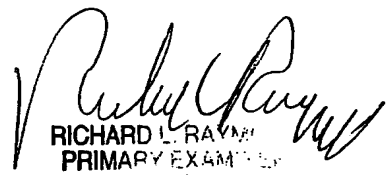
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671.

The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sudhaker B. Patel, D.Sc. Tech.
April 20, 2004


RICHARD L. RAY
PRIMARY EXAMINER
ART UNIT 1624
MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624/1623



Interview Summary

Application No.

10/016,280

Applicant(s)

HIMMELSBACH ET AL

Examiner

Sudhaker B. Patel,
D.Sc.Tech.

Art Unit

1624

All participants (applicant, applicant's representative, PTO personnel):

(1) Sudhaker B. Patel, D.Sc.Tech.

(3) _____

(2) ATTY.S.K.Pocchiari.

(4) _____

Date of Interview: 20 April 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____

Claim(s) discussed: 1-9, 12 and 13.

Identification of prior art discussed: None.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner initiated the discussion by calling the applicants to inform them that the instant application is not ready for allowance in the as is stage. The Foreign priority papers' certified copies are not in the e-DAN file received by the examiner. Applicants were urged to provide the same. FR will be mailed for applicants' review with their clients abroad and reply to Office.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an
Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Notice of References Cited

Application/Control No.

10/016,280

Applicant(s)/Patent Under
Reexamination
HIMMELSBACH ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

Art Unit

1624

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	9909016	02-1999	WO	Wissner et al	_____
*	O	9738983	10-1997	WO	Bridges et al	_____
*	P	566226	10-1993	EP	Barker et al	_____
	Q					
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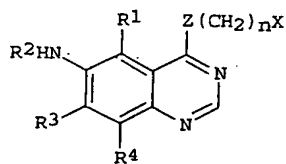
NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Chemical Abstract DN 130:196664, also cited as WO9909016.
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	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

L8 ANSWER 9 OF 9 CAPLUS COPYRIGHT 2004 ACS on STN
 AN 1999:139837 PLUS
 DN 130:196664
 TI Preparation of 4-phenylaminoquinazolin-6-ylamides and related compounds as tyrosine kinase inhibitors.
 IN Wissner, Allan; Tsou, Hwei-ru; Johnson, Bernard Dean; Hamann, Philip Ross; Zhang, Nan
 PA American Cyanamid Company, USA
 SO PCT Int. Appl., 121 pp.
 CODEN: PIXXD2
 DT Patent
 LA English
 FAN.CNT 1

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
PI	WO 9909016	A1	19990225	WO 1998-US15789	19980729
	W: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM				
	RW: GH, GM, KE, LS, MW, SD, SZ, UG, ZW, AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG				
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				US 1997-904942 A	19970801
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	EP 1000039	A1	20000517	EP 1998-937275	19980729
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, PT, IE, SI, LT, LV, FI, RO				
				US 1997-904942 A	19970801
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	NO 2000000487	A	20000331	NO 2000-487	20000131
				US 1997-904942 A	19970801
				WO 1998-US15789W	19980729
OS	MARPAT 130:196664				
GI					



AB Title compds. [I; X = (substituted) cycloalkyl, pyridinyl, pyrimidinyl, Ph; Z = NH, O, S, NR; R = alkyl; R1, R3, R4 = H, halo, alkyl, alkenyl, alkenyl, alkenyloxy, alkynyloxy, CH2OH, halomethyl, alkanoyloxy, alkenoyloxy, alkynoyloxy, alkanoyloxymethyl, etc.; R2 = R5C.tplbond.CCO, (R5)2C:CR5CO, R5SS[C(R5)2]rCO, etc.; n = 0, 1; r = 1-4; R5 = H, CO2H, carboalkoxy, Ph, etc.], were prepared Thus, 4-dimethylamino-2-butyric acid (preparation given) was stirred with iso-Bu chloroformate and N-methylmorpholine in THF with ice cooling; N-(3-bromophenyl)-4,6-quinazolinediamine in pyridine was added and the mixture was stirred 2 h at 0° to give 4-dimethylamino-2-butyric acid [4-(3-bromophenylamino)quinazolin-6-yl]amide. The latter inhibited MB435 tumor cell growth with IC50 = 0.05 µg/mL.
 RE.CNT 5 THERE ARE 5 CITED REFERENCES AVAILABLE FOR THIS RECORD
 ALL CITATIONS AVAILABLE IN THE RE FORMAT

APPLICANT(S): Himmelsbach, et al
SERIAL NO.: 10/016,280
FILING DATE: December 10, 2001
DOCKET NO.: 5/1262
TITLE: Bicyclic heterocycles, pharmaceutical
compositions containing these compounds, their use and
processes for preparing them

IN CONNECTION WITH THE ABOVE CASE, PLEASE
DATE STAMP TO ACKNOWLEDGE RECEIPT OF THE
DOCUMENTS LISTED BELOW, AND RETURN TO
ADDRESSEE.

1. Reply after Final with Amendment (16 pages)
2. Notice of Appeal (1 page in triplicate)
3. Petition for Extension of Time (1 page in triplicate)
4. Priority Document #199 28 281.1 and #100 23 085.7

Mailed: October 21, 2004



Serial No. 10/016,280

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Himmelsbach, F. et al) Art Unit: 1624
Serial No. : 10/016,280) Examiner: Patel, S.
Confirmation No. : 7351
Filed : December 10, 2001
For : Bicyclic heterocycles, pharmaceutical compositions
containing these compounds, their use and processes
for preparing them
Docket No. : 5/1262

Mail Stop - AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY AFTER FINAL WITH AMENDMENT UNDER 37 U.S.C. § 1.116

Sir:

In response to the Office Action mailed on April 23, 2004, please consider the remarks and enter the amendments below. Submitted herewith is: (a) a Petition for Extension of Time for three months up to and including October 23, 2004, together with the necessary fee; (b) a Notice of Appeal, with fee; and (c) certified true copies of priority applications Germany 19928281.1 and Germany 10023085.7.

Amendments to the claims are reflected in the listing of claims which begins on page 2 of this paper.

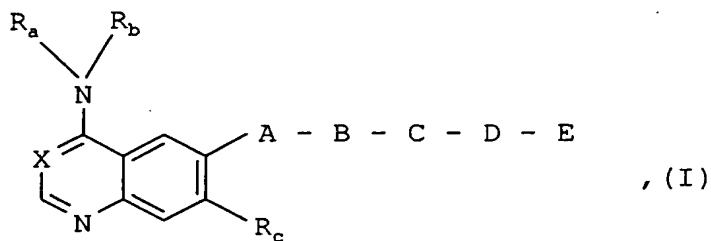
Remarks begin on page 13 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions and listing of claims in the application:

Listing of Claims:

1. (currently amended) A quinazoline compound of formula



wherein

R_a denotes a hydrogen atom or a C₁₋₄-alkyl group,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ to R₃, whilst

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C₁₋₄-alkyl, hydroxy, C₁₋₄-alkoxy, C₃₋₆-cycloalkyl, C₄₋₆-cycloalkoxy, C₂₋₅-alkenyl or C₂₋₅-alkynyl group,

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a C₃₋₅-alkenyloxy or C₃₋₅-alkynyloxy group, whilst the unsaturated moiety may not be linked to the oxygen atom,

a C₁₋₄-alkylsulfenyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, C₁₋₄-alkylsulfonyloxy, trifluoromethylsulfenyl, trifluoromethylsulfinyl or trifluoromethylsulfonyl group,

a methyl or methoxy group substituted by 1 to 3 fluorine atoms,

an ethyl or ethoxy group substituted by 1 to 5 fluorine atoms,

a cyano or nitro group or an amino group optionally substituted by one or two C₁₋₄-alkyl groups, wherein the substituents may be identical or different, or

R₁ together with R₂, if they are bound to adjacent carbon atoms, denote a -CH=CH-CH=CH group and

R₃ denotes a hydrogen, fluorine, chlorine or bromine atom,

a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,

X denotes a nitrogen atom,

A denotes an imino group optionally substituted by a C₁₋₄-alkyl group,

B denotes a carbonyl group,

C denotes a ~~1,3-allenylene~~ ~~-CH=C=CH-~~, ~~1,1-~~ ~~>C=CH₂~~ or ~~1,2-vinylene~~ ~~-CH=CH-~~ group which may be substituted in each case by one or two methyl groups or by a trifluoromethyl group,

~~an-ethynylene~~ ~~-C≡C-~~ group or

~~a-1,3-butadien-1,4-ylene~~ ~~-CH=CH-CH=CH-~~ group optionally substituted by 1 to 4 methyl groups or by a trifluoromethyl group,

D denotes an alkylene group wherein the alkylene moiety contains 1 to 8 carbon atoms and additionally 1 to 4 hydrogen atoms in the alkylene moiety may be replaced by fluorine atoms,

E denotes an amino, C₁₋₄-alkylamino or di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

a C₂₋₄-alkylamino group wherein the alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst

R₅ denotes a hydroxy, C₁₋₄-alkoxy, amino, C₁₋₄-alkylamino or di-(C₁₋₄-alkyl)-amino group,

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst R₅ is as hereinbefore defined,

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties are substituted in each case in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst the substituents may be identical or different and R₅ is as hereinbefore defined,

a C₃₋₇-cycloalkylamino or C₃₋₇-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom may be substituted by a further C₁₋₄-alkyl group,

R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₆-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl, hydroxy, C₁₋₄-alkoxy, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, hydroxy-C₁₋₂-alkyl, C₁₋₄-alkoxy-C₁₋₂-alkyl, amino-C₁₋₂-alkyl, C₁₋₄-alkylamino-C₁₋₂-alkyl, or di-(C₁₋₄-alkyl)-amino-C₁₋₂-alkyl group, whilst the abovementioned monosubstituted cycloalkyl moieties may additionally be substituted by a C₁₋₃-alkyl group,

whilst

by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which in each case may be monosubstituted by R₇, mono-, di- or trisubstituted by R₈ or monosubstituted by R₇ and additionally mono- or disubstituted by R₈, wherein the substituents may be identical or different and

R₇ denotes a cyano, carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl, di-(C₁₋₄-alkyl)-aminocarbonyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, hydroxy, C₁₋₄-alkylsulfonyloxy, trifluoromethyloxy, nitro, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, C₁₋₄-alkylcarbonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylcarbonylamino, C₁₋₄-alkylsulfonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylsulfonylamino, aminosulfonyl, C₁₋₄-alkylaminosulfonyl or di-(C₁₋₄-alkyl)-aminosulfonyl group, and

R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group or

two groups R₈, if they are bound to adjacent carbon atoms, together denote a C₃₋₅-alkylene or 1,3-butadien-1,4-ylene group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

2. (currently amended) A quinazoline of formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ to R₃, whilst

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C₁₋₄-alkyl, hydroxy, C₁₋₄-alkoxy, C₃₋₆-cycloalkyl, C₄₋₆-cycloalkoxy, C₂₋₅-alkenyl or C₂₋₅-alkynyl group,

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a methyl or methoxy group substituted by 1 to 3 fluorine atoms,

a cyano or nitro group and

R₃ denotes a hydrogen, fluorine, chlorine or bromine atom,

a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a ~~1,3-allenylene~~ -CH=C=CH-, ~~1,1-~~ >C=CH₂ or ~~1,2-vinylene~~ -CH=CH- group,

an ~~ethynylene~~ -C≡C- or ~~1,3-butadien-1,4-ylen~~ -CH=CH-CH=CH- group,

D denotes an alkylene group wherein the alkylene moiety in each case contains 1 to 4 carbon atoms and additionally 1 to 4 hydrogen atoms in the alkylene moiety may be replaced by fluorine atoms,

E denotes a di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β-, γ-, or δ-position with regard to the nitrogen atom of the amino group by the group R₅, where

R₅ denotes a hydroxy, C₁₋₄-alkoxy or di-(C₁₋₄-alkyl)-amino group,

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties in each case are substituted in β-, γ-, or δ-position with regard to the nitrogen atom of the amino group by the group R₅, wherein the substituents may be identical or different and R₅ is as hereinbefore defined,

a C₃₋₇-cycloalkylamino or C₃₋₇-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom is substituted by a further C₁₋₄-alkyl group,

R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₆-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl, hydroxy, C₁₋₄-alkoxy, di-(C₁₋₄-alkyl)-amino, hydroxy-C₁₋₂-alkyl, C₁₋₄-alkoxy-C₁₋₂-alkyl, or di-(C₁₋₄-alkyl)-amino-C₁₋₂-alkyl group, whilst the abovementioned monosubstituted cycloalkyl moieties may additionally be substituted by a C₁₋₃-alkyl group, , whilst

by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which may in each case be monosubstituted by R₇, mono-, di- or trisubstituted by R₈ or monosubstituted by R₇ and additionally mono- or disubstituted by R₈, wherein the substituents may be identical or different and

R₇ denotes a cyano, carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl, di-(C₁₋₄-alkyl)-aminocarbonyl, C₁₋₄-alkylsulfenyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, hydroxy, C₁₋₄-alkylsulfonyloxy, trifluoromethyloxy, nitro, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, C₁₋₄-alkylcarbonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylcarbonylamino, C₁₋₄-alkylsulfonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylsulfonylamino, aminosulfonyl, C₁₋₄-alkylaminosulfonyl or di-(C₁₋₄-alkyl)-aminosulfonyl group, and

R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group or

two groups R₈, if they are bound to adjacent carbon atoms, together denote a C₃₋₅-alkylene or 1,3-butadien-1,4-ylene group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

3. (currently amended) A quinazoline of formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R_1 and R_2 , where

R_1 and R_2 , which may be identical or different, in each case denote a hydrogen, fluorine, chlorine or bromine atom,

a methyl, trifluoromethyl or methoxy group,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a ~~1,2-vinylene~~ $\text{CH}=\text{CH}$ - group,

an-ethynylene $\text{C}\equiv\text{C}$ - or ~~1,3-butadien-1,4-ylen~~ $\text{CH}=\text{CH}-\text{CH}=\text{CH}$ - group,

D denotes a C_{1-4} -alkylene group,

E denotes a di- $(\text{C}_{1-4}\text{-alkyl})$ -amino group wherein the alkyl moieties may be identical or different,

an N- $(\text{C}_{1-4}\text{-alkyl})$ -N- $(\text{C}_{2-4}\text{-alkyl})$ -amino group wherein the C_{2-4} -alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R_5 , whilst

R_5 denotes a hydroxy, C_{1-3} -alkoxy or di- $(\text{C}_{1-3}\text{-alkyl})$ -amino group,

a di- $(\text{C}_{2-4}\text{-alkyl})$ -amino group wherein the two C_{2-4} -alkyl moieties in each case are substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R_5 , wherein the substituents may be identical or different and R_5 is as hereinbefore defined,

a C₃₋₅-cycloalkylamino or C₃₋₅-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom is substituted by a further C₁₋₃-alkyl group,

R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₄-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl or C₁₋₃-alkoxy group, or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

4. (currently amended) A quinazoline of formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group, whilst the phenyl nucleus is substituted in each case by the radicals R₁ and R₂, whilst

R₁ and R₂, which may be identical or different, each denotes a hydrogen, fluorine, chlorine or bromine atom,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a ~~1,2-vinylene~~ -CH=CH-, ~~ethynylene~~ -C≡C- or ~~1,3-butadien-1,4-ylene~~ -CH=CH-CH=CH- group,

D denotes an C₁₋₃-alkylene group,

E denotes a Di-(C₁₋₄-alkyl)-amino group, wherein the alkyl moieties may be identical or different,

a methylamino or ethylamino group each substituted at the nitrogen atom by a 2-methoxyethyl, 1-methoxy-2-propyl, 2-methoxypropyl, 3-methoxypropyl, cyclopropyl or cyclopropylmethyl group,

a bis-(2-methoxyethyl)amino group,

R_c denotes a cyclopropylmethoxy, cyclobutylmethoxy, cyclopentylmethoxy or cyclohexylmethoxy group,

a cyclobutyloxy, cyclopentyloxy or cyclohexyloxy group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

5. (currently amended) A quinazoline of formula I according to claim 1, wherein

R_a denotes a hydrogen atom,

R_b denotes a 1-phenylethyl group or a phenyl group wherein the phenyl nucleus is substituted by the radicals R₁ and R₂, whilst

R₁ and R₂, which may be identical or different, each denote a hydrogen, fluorine, chlorine or bromine atom,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a ~~1,2-vinylene -CH=CH-~~ ethynylene -C≡C- or ~~1,3-butadien-1,4-ylene -CH=CH-~~ CH=CH- group,

D denotes a methylene group,

E denotes a dimethylamino, diethylamino, Bis(2-methoxyethyl)amino, *N*-methyl-*N*-(2-methoxyethyl)amino, *N*-ethyl-*N*-(2-methoxyethyl)amino, *N*-methyl-*N*-cyclopropylamino, *N*-methyl-*N*-cyclopropylmethyl-amino, *N*-methyl-*N*-(1-methoxy-2-propyl)amino, *N*-methyl-*N*-(2-methoxypropyl)amino or *N*-methyl-*N*-(3-methoxypropyl)amino, *N*-methyl-*N*-(tetrahydrofuran-3-yl)amino, *N*-methyl-*N*-(tetrahydropyran-4-yl)amino group,

R_c denotes a cyclopropylmethoxy, cyclobutyloxy or cyclopentyloxy group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

6. (previously presented) The following compounds of general formula I according to claim 1:

4-[(3-Chloro-4-fluorophenyl)amino]-6-[[4-(*N,N*-diethylamino)-1-oxo-2-buten-1-yl]amino]-7-cyclopropylmethoxyquinazoline

or pharmaceutically acceptable salts thereof.

7. (previously presented) Pharmaceutically acceptable salts of the compounds according to one of claims 1 to 6 with inorganic or organic acids or bases.

8. (currently amended) Pharmaceutical composition containing a compound according to at least one of claims 1 to 6, optionally together with ~~one or more inert carriers and/or diluents~~ an inert carrier and with or without a diluent.

9. (currently amended) A method for treating ~~or preventing~~ a disease comprising administering a pharmaceutical composition according to one of claims 1 to 6, wherein said disease is selected from the group consisting of: ~~benign or malignant tumors~~, diseases of the airways and lungs and diseases of the gastrointestinal tract and the bile duct and gall bladder.

Claims 10-11 (canceled)

12. (currently amended) Pharmaceutical compositions containing a physiologically acceptable salt according to claim 7, optionally together with ~~one or more inert carriers and/or diluents~~ an inert carrier and with or without a diluent.

13. (currently amended) A method for treating ~~or preventing~~ a disease comprising administering a pharmaceutical composition according to claim 7, wherein said disease is selected from the group consisting of: ~~benign or malignant tumors~~, diseases of the airways and lungs and diseases of the gastrointestinal tract and the bile duct and gall bladder.

REMARKS

Claims 1-9, 12 and 13 are currently pending in the instant application. Claims 1-5, 8, 9, 12, and 13 have been amended. Claims 1-5 have been amended to recite the structures of variable C. Claims 8 and 12 have been amended to recite "an inert carrier and with or without a diluent". Claims 9 and 13 been amended delete the phrases "or preventing" and "benign or".

No new matter has been added. In light of the above amendments, claims 1-9, 12 and 13 are under active consideration in this application.

Interview Summary

Examiner, Sudhaker B. Patel, initiated a telephonic interview with Attorney for Applicants, Susan K. Pocchiari, on April 20, 2004 wherein claims 1-9, 12 and 13 were discussed. Agreement with respect to the claims was not reached. No exhibits or prior art were discussed. The Examiner informed Attorney that the claims were not ready for allowance in their present state. The Examiner also informed Attorney that certified copies of the foreign priority applications are not in the e-DAN file received by the Examiner. Attorney for Applicants agreed to provide said certified copies (attached hereto). Due to a lack of availability of Applicants, the Examiner agreed to mail a Final Office Action for Attorney's review with Applicants abroad and for preparation of a response.

Priority

The Examiner has indicated that the records and the eDAN electronic file as received by the Examiner for the instant application are missing the certified true copies of German Application Nos. DE 199 28 281 and DE 100 23 085, filed June 21, 1999 and May 11, 2000, respectively, to which the instant application claims priority.

Submitted herewith are certified true copies of German Application Nos. DE 199 28 281 and DE 100 23 085, filed June 21, 1999 and May 11, 2000.

Rejections under Section 112

According to the Examiner, the rejection of claims 1-5, 7, 8, 9, 12, 13 under 35 U.S.C. §112, second paragraph as being indefinite are maintained for reasons already stated in prior Office communication paper dated July 8, 2003.

As a preliminary matter, Applicants respectfully point out that only claims 1-7 were rejected under Section 112, second paragraph in the prior Office communication dated July 8, 2003. Further, Applicants respectfully submit that claims 1-7 were amended according to the Examiner's suggestions in the Response filed January 8, 2004. Applicants respectfully request that the rejections under Section 112, second paragraph in the prior Office communication be withdrawn.

The Examiner cites the following additional reasons for rejection of claims 1-9, 12, and 13 under 35 U.S.C. §112, second paragraph as being indefinite.

According to the Examiner, claim 1 is indefinite in the recitation of variable C as "1,3-allenylene, 1,1- or 1,2-vinylene".

Applicants disagree and submit that the terms are clear and are commonly used terms that can be found in chemistry textbooks. However, claim 1 has been amended to recite the chemical structures of 1,3-allenylene, 1,1-vinylene and 1,2-vinylene. Applicants submit that one skilled in the art would know that 1,3-allenylene is $-\text{CH}=\text{C}=\text{CH}-$ (allenyl group (from allene) substituted (by B and D, respectively) in position 1 and 3; the "-ene" signifying that the rest has two binding sites (for example, methyl: $-\text{CH}_3$; methylene: $-\text{CH}_2-$)). Further, Applicants submit that one skilled in the art would know that 1,1-vinylene means $>\text{C}=\text{CH}_2$ and 1,2-vinylene means $-\text{CH}=\text{CH}-$. Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner, claims 1 and 3 are indefinite in the recitation of variable C as "1,3-butadien-1,4-ylene".

Applicants disagree and submit that the term is clear and is a commonly used term that can be found in chemistry textbooks. However, claims 1 and 3 have been amended to recite the chemical structure of 1,3-butadien-1,4-ylene as $-\text{CH}=\text{CH}-\text{CH}=\text{CH}-$ (1,3-butadiene as the Examiner pointed out, to which B and D, respectively, are linked in positions 1 and 4 (*i.e.*, instead of a hydrogen atom in the pure compound); in spite of the different resulting name of the entire molecule, the rest is exemplified for example, in Example 2, wherein B is carbonyl and D and E together are methyl). Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner, claims 1 and 3 are indefinite in the recitation of variable C as “ethynylene”.

Applicants disagree and submit that the term is clear and is a commonly used term that can be found in chemistry textbooks. However, claims 1 and 3 have been amended to recite the chemical structure of ethynylene as $\text{—C}\equiv\text{C—}$, *i.e.*, acetylene, bond to B on the one side/carbon atom and to D on the other side/carbon atom. Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner, claims 9 and 13 are indefinite in the recitation “or preventing”

Applicants disagree. However, claims 9 and 13 have been amended to delete the phrase “or preventing”. Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner claim 12 is indefinite in the recitation “with one or more inert carriers and/or diluents”.

Applicants disagree. However, claims 8 and 12 have been amended according to the Examiner’s suggestion to recite “an inert carrier and with or without a diluent”. Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner claim 12 is indefinite in the recitation “with one or more inert carriers and/or diluents”.

Applicants disagree. However, claims 8 and 12 have been amended according to the Examiner’s suggestion to recite “an inert carrier and with or without a diluent”. Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner claims 9 and 13 are indefinite in the recitation “benign or malignant tumors”.

Applicants disagree. However, claims 9 and 13 have been amended according to the Examiner's suggestion to recite a single tumor, *i.e.*, "malignant tumors". Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

According to the Examiner claims 1-9 are difficult to read what is exactly claimed.

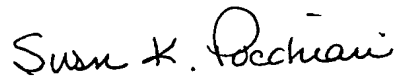
Applicants disagree. However, claims 1-9 have been amended to replace the definitions of variable C by the respective chemical formula. Applicants submit that in light of the above amendments and remarks, this rejection under Section 112 has been overcome.

Applicants submit that in light of the amendments and remarks above, all of the rejections under Section 112, second paragraph have been overcome and must be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that all of the objections and rejections have been overcome and must be withdrawn. Further, Applicants submit that the application is now in form for issuance and an early allowance is earnestly requested. If any issues remain, the Examiner is invited to telephone the Attorney at the number below.

Respectfully submitted,




Susan K. Pocchiari
Attorney for Applicant(s)
Reg. No. 45,016

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT. 06877
Tel.: (203) 798-5648
October 21, 2004

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Docket Number (Optional)

5/1262

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Signature Susan K. PocchiariTyped or printed name Susan K. PocchiariIn re Application of
Himmelsbach, F. et al.Application Number
10/016,280Filed
December 10, 2001For **Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them**Art Unit
1624Examiner
Patel, Sudhaker B.

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1))

\$ 340.00

- ☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: \$ _____
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- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 02-2955. I have enclosed a duplicate copy of this sheet.
- ☒ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

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I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)
- ☒ attorney or agent of record. 45,016
Registration number _____
- ☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34. _____

Susan K. Pocchiari
SignatureSusan K. Pocchiari
Typed or printed name203-798-5648
Telephone numberOctober 21, 2004
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 3 forms are submitted.

This collection of information is required by 37 CFR 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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For Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2005 (fees effective on or after October 1, 2004)		Docket Number (Optional) 5/1262	
Application Number 10/016,280		Filed December 10, 2001	
For Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them			
Art Unit 1624		Examiner Patel, S.	

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The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$110	\$55	\$ _____
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<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$980	\$490	\$ <u>980.00</u>
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Susan K. Pocchiari
Signature

October 21, 2004
Date

Susan K. Pocchiari Reg #45,016
Typed or printed name

203-798-5648
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Registration number if acting under 37 CFR 1.34 _____		
<u>Susan K. Pocchiarri</u> Signature		<u>October 21, 2004</u> Date
<u>Susan K. Pocchiarri Reg #45,016</u> Typed or printed name		<u>203-798-5648</u> Telephone Number

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BUNDESREPUBLIK DEUTSCHLAND



Prioritätsbescheinigung über die Einreichung einer Patentanmeldung

Aktenzeichen: 199 28 281.1

Anmeldetag: 21. Juni 1999

Anmelder/Inhaber: Boehringer Ingelheim Pharma GmbH & Co KG,
55218 Ingelheim/DE

(vormals: Boehringer Ingelheim Pharma KG)

Bezeichnung: Bicyclische Heterocyclen, diese Verbindungen
enthaltende Arzneimittel, deren Verwendung
und Verfahren zu ihrer Herstellung

IPC: C 07 D, A 61 K

Die angehefteten Stücke sind eine richtige und genaue Wiedergabe der ursprünglichen Unterlagen dieser Patentanmeldung.

München, den 15. September 2004
Deutsches Patent- und Markenamt
Der Präsident
Im Auftrag

Ebert

BUNDESREPUBLIK DEUTSCHLAND



Prioritätsbescheinigung über die Einreichung einer Patentanmeldung

Aktenzeichen: 100 23 085.7

Anmeldetag: 11. Mai 2000

Anmelder/Inhaber: BOEHRINGER INGELHEIM PHARMA KG,
Ingelheim/DE

Bezeichnung: Bicyclische Heterocyclen, diese Verbindungen
enthaltende Arzneimittel, deren Verwendung und
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IPC: C 07 D, A61 K

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München, den 6. Juli 2000
Deutsches Patent- und Markenamt
Der Präsident
Im Auftrag

Nietiedt

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EFS ID:	1008627
Application Number:	10016280
Confirmation Number:	7351
Title of Invention:	Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them
First Named Inventor:	Frank Himmelsbach
Customer Number:	28505
Filer:	Paula Wittmayer/Susan Wasilko
Filer Authorized By:	Paula Wittmayer
Attorney Docket Number:	5/1262
Receipt Date:	13-MAR-2006
Filing Date:	10-DEC-2001
Time Stamp:	14:59:00
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 450.0
RAM confirmation Number	5
Deposit Account	022955
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1		5-1262-ROA-03-13-06.pdf	144482	yes	15

	Multipart Description				
	Doc Desc		Start	End	
	Amendment After Final		1	1	
	Claims		2	12	
	Applicant Arguments/Remarks Made in an Amendment		13	15	

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	8190	no	2
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Warnings:

Information:

Total Files Size (in bytes):	152672
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

Electronic Patent Application Fee Transmittal

Application Number:	10016280			
Filing Date:	10-Dec-2001			
Title of Invention:	Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them			
First Named Inventor:	Frank Himmelsbach			
Filer:	Paula Wittmayer/Susan Wasilko			
Attorney Docket Number:	5/1262			
Filed as Large Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with \$0 paid	1252	1	450	450

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				450

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Frank Himmelsbach, et al) Confirm. No.: 7351
Serial No.: 10/016,280) Art Unit: 1624
Filed: December 10, 2001) Examiner: Tamthom N. Truong
For: Bicyclic heterocycles, pharmaceutical compositions containing these
compounds, their use and processes for preparing them
Docket No.: 5/1262

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

This is in response to a communication from the Examiner in charge of the subject application, which communication was mailed on October 12, 2005. In that Office Action, a three-month shortened statutory period was set for response. Applicants hereby petition for the necessary two-month extension of time under 37 C.F.R. § 1.136 to respond to that action and note that the fee required under 37 C.F.R. § 1.17(a) in connection with this Reply will be paid during electronic filing via the Revenue Accounting and Management System.

Listing of the Claims begin on page two (2) of this paper.

Remarks/Arguments begin on page thirteen (13) of this paper.

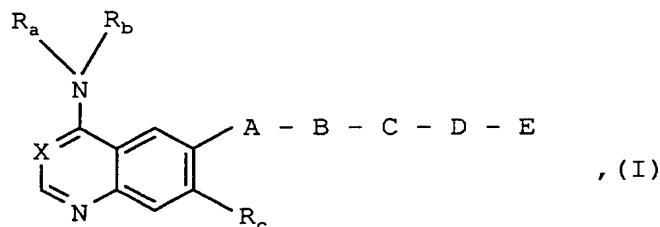
CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-13 (canceled)

Claim 14 (previously presented) A quinazoline compound of formula



wherein

R_a denotes a hydrogen atom or a C₁₋₄-alkyl group,

benzyl, 1-phenylethyl or 3-phenylpropyl

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ to R₃, whilst

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C₁₋₄-alkyl, hydroxy, C₁₋₄-alkoxy, C₃₋₆-cycloalkyl, C₄₋₆-cycloalkoxy, C₂₋₅-alkenyl or C₂₋₅-alkynyl group,

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a C₃₋₅-alkenyloxy or C₃₋₅-alkynyloxy group, whilst the unsaturated moiety may not be linked to the oxygen atom,

a C₁₋₄-alkylsulfenyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, C₁₋₄-alkylsulfonyloxy, trifluoromethylsulfenyl, trifluoromethylsulfinyl or trifluoromethylsulfonyl group,

a methyl or methoxy group substituted by 1 to 3 fluorine atoms,

an ethyl or ethoxy group substituted by 1 to 5 fluorine atoms,

a cyano or nitro group or an amino group optionally substituted by one or two C₁₋₄-alkyl groups, wherein the substituents may be identical or different, or

R₁ together with R₂, if they are bound to adjacent carbon atoms, denote a -CH=CH-CH=CH group and

R₃ denotes a hydrogen, fluorine, chlorine or bromine atom,

a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,

N ✓X denotes a nitrogen atom,

A denotes an imino group optionally substituted by a C₁₋₄-alkyl group,



✓B denotes a carbonyl group,

C denotes a -CH=C=CH-, >C=CH₂ or -CH=CH- group which may be substituted in each case by one or two methyl groups or by a trifluoromethyl group,

an -C≡C- group or

a -CH=CH-CH=CH- group optionally substituted by 1 to 4 methyl groups or by a trifluoromethyl group,

D denotes an alkylene group wherein the alkylene moiety contains 1 to 8 carbon atoms and additionally 1 to 4 hydrogen atoms in the alkylene moiety may be replaced by fluorine atoms,

E denotes an amino, C₁₋₄-alkylamino or di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

a C₂₋₄-alkylamino group wherein the alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst

R₅ denotes a hydroxy, C₁₋₄-alkoxy, amino, C₁₋₄-alkylamino or di-(C₁₋₄-alkyl)-amino group,

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst R₅ is as hereinbefore defined,

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties are substituted in each case in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, whilst the substituents may be identical or different and R₅ is as hereinbefore defined,

a C₃₋₇-cycloalkylamino or C₃₋₇-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom may be substituted by a further C₁₋₄-alkyl group,

R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₆-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl, hydroxy, C₁₋₄-alkoxy, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, hydroxy-C₁₋₂-alkyl, C₁₋₄-alkoxy-C₁₋₂-alkyl, amino-C₁₋₂-alkyl, C₁₋₄-alkylamino-C₁₋₂-alkyl, or di-(C₁₋₄-alkyl)-amino-C₁₋₂-alkyl group, whilst the abovementioned monosubstituted cycloalkyl moieties may additionally be substituted by a C₁₋₃-alkyl group,

whilst

by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which in each case may be monosubstituted by R₇, mono-, di- or trisubstituted by R₈ or monosubstituted by R₇ and additionally mono- or disubstituted by R₈, wherein the substituents may be identical or different and

R₇ denotes a cyano, carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl, di-(C₁₋₄-alkyl)-aminocarbonyl, C₁₋₄-alkylsulfenyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, hydroxy, C₁₋₄-alkylsulfonyloxy, trifluoromethyloxy, nitro, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, C₁₋₄-alkyl-carbonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylcarbonylamino, C₁₋₄-alkylsulfonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylsulfonylamino, aminosulfonyl, C₁₋₄-alkylaminosulfonyl or di-(C₁₋₄-alkyl)-aminosulfonyl group, and

R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group or

two groups R₈, if they are bound to adjacent carbon atoms, together denote a C₃₋₅-alkylene or 1,3-butadien-1,4-ylene group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

Claim 15 (previously presented) The quinazoline of formula I according to claim 14, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ to R₃, whilst

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C₁₋₄-alkyl, hydroxy, C₁₋₄-alkoxy, C₃₋₆-cycloalkyl, C₄₋₆-cycloalkoxy, C₂₋₅-alkenyl or C₂₋₅-alkynyl group,

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a methyl or methoxy group substituted by 1 to 3 fluorine atoms,

a cyano or nitro group and

R₃ denotes a hydrogen, fluorine, chlorine or bromine atom,

a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a -CH=C=CH-, >C=CH₂ or -CH=CH- group,

an -C≡C- or -CH=CH-CH=CH- group,

D denotes an alkylene group wherein the alkylene moiety in each case contains 1 to 4 carbon atoms and additionally 1 to 4 hydrogen atoms in the alkylene moiety may be replaced by fluorine atoms,

E denotes a di-(C₁₋₄-alkyl)-amino group wherein the alkyl moieties may be identical or different,

an N-(C₁₋₄-alkyl)-N-(C₂₋₄-alkyl)-amino group wherein the C₂₋₄-alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, where

R₅ denotes a hydroxy, C₁₋₄-alkoxy or di-(C₁₋₄-alkyl)-amino group,

a di-(C₂₋₄-alkyl)-amino group wherein the two C₂₋₄-alkyl moieties in each case are substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R₅, wherein the substituents may be identical or different and R₅ is as hereinbefore defined,

a C₃₋₇-cycloalkylamino or C₃₋₇-cycloalkyl-C₁₋₃-alkylamino group wherein in each case the nitrogen atom is substituted by a further C₁₋₄-alkyl group,

R_c denotes a C₄₋₇-cycloalkoxy or C₃₋₇-cycloalkyl-C₁₋₆-alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C₁₋₃-alkyl, hydroxy, C₁₋₄-alkoxy, di-(C₁₋₄-alkyl)-amino, hydroxy-C₁₋₂-alkyl, C₁₋₄-alkoxy-C₁₋₂-alkyl, or di-(C₁₋₄-alkyl)-amino-C₁₋₂-alkyl group, whilst the abovementioned monosubstituted cycloalkyl moieties may additionally be substituted by a C₁₋₃-alkyl group, , whilst

by the aryl moieties mentioned in the definition of the abovementioned groups is meant a phenyl group which may in each case be monosubstituted by R₇, mono-, di- or trisubstituted by R₈ or monosubstituted by R₇ and additionally mono- or disubstituted by R₈, wherein the substituents may be identical or different and

R₇ denotes a cyano, carboxy, C₁₋₄-alkoxycarbonyl, aminocarbonyl, C₁₋₄-alkylaminocarbonyl, di-(C₁₋₄-alkyl)-aminocarbonyl, C₁₋₄-alkylsulfenyl, C₁₋₄-alkylsulfinyl, C₁₋₄-alkylsulfonyl, hydroxy, C₁₋₄-alkylsulfonyloxy, trifluoromethyloxy, nitro, amino, C₁₋₄-alkylamino, di-(C₁₋₄-alkyl)-amino, C₁₋₄-alkyl-carbonylamino, N-(C₁₋₄-alkyl)-C₁₋₄-alkylcarbonylamino, C₁₋₄-alkylsulfonylamino,

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

N-(C₁₋₄-alkyl)-C₁₋₄-alkylsulfonylamino, aminosulfonyl, C₁₋₄-alkylaminosulfonyl or di-(C₁₋₄-alkyl)-aminosulfonyl group, and

R₈ denotes a fluorine, chlorine, bromine or iodine atom, a C₁₋₄-alkyl, trifluoromethyl or C₁₋₄-alkoxy group or

two groups R₈, if they are bound to adjacent carbon atoms, together denote a C₃₋₅-alkylene or 1,3-butadien-1,4-ylene group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

Claim 16 (previously presented) The quinazoline of formula I according to claim 14, wherein

R_a denotes a hydrogen atom,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R₁ and R₂, where

R₁ and R₂, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine or bromine atom,

a methyl, trifluoromethyl or methoxy group,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a -CH=CH- group,

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

an $\text{-C}\equiv\text{C-}$ or -CH=CH-CH=CH- group,

D denotes a C_{1-4} -alkylene group,

E denotes a di- $(\text{C}_{1-4}$ -alkyl)-amino group wherein the alkyl moieties may be identical or different,

an N- $(\text{C}_{1-4}$ -alkyl)-N- $(\text{C}_{2-4}$ -alkyl)-amino group wherein the C_{2-4} -alkyl moiety is substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R_5 , whilst

R_5 denotes a hydroxy, C_{1-3} -alkoxy or di- $(\text{C}_{1-3}$ -alkyl)-amino group,

a di- $(\text{C}_{2-4}$ -alkyl)-amino group wherein the two C_{2-4} -alkyl moieties in each case are substituted in β -, γ -, or δ -position with regard to the nitrogen atom of the amino group by the group R_5 , wherein the substituents may be identical or different and R_5 is as hereinbefore defined,

a C_{3-5} -cycloalkylamino or C_{3-5} -cycloalkyl- C_{1-3} -alkylamino group wherein in each case the nitrogen atom is substituted by a further C_{1-3} -alkyl group,

R_c denotes a C_{4-7} -cycloalkoxy or C_{3-7} -cycloalkyl- C_{1-4} -alkoxy group wherein the cycloalkyl moiety in each case may be substituted by a C_{1-3} -alkyl or C_{1-3} -alkoxy group, or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

Claim 17 (previously presented) The quinazoline of formula I according to claim 14, wherein

R_a denotes a hydrogen atom,

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

R_b denotes a phenyl, benzyl or 1-phenylethyl group, whilst the phenyl nucleus is substituted in each case by the radicals R₁ and R₂, whilst

R₁ and R₂, which may be identical or different, each denotes a hydrogen, fluorine, chlorine or bromine atom,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a -CH=CH-, -C≡C- or -CH=CH-CH=CH- group,

D denotes an C₁₋₃-alkylene group,

E denotes a di-(C₁₋₄-alkyl)-amino group, wherein the alkyl moieties may be identical or different,

a methylamino or ethylamino group each substituted at the nitrogen atom by a 2-methoxyethyl, 1-methoxy-2-propyl, 2-methoxypropyl, 3-methoxypropyl, cyclopropyl or cyclopropylmethyl group,

a bis-(2-methoxyethyl)amino group,

R_c denotes a cyclopropylmethoxy, cyclobutylmethoxy, cyclopentylmethoxy or cyclohexylmethoxy group,

a cyclobutyloxy, cyclopentyloxy or cyclohexyloxy group,
or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

Claim 18 (previously presented) The quinazoline of formula I according to claim 14, wherein

R_a denotes a hydrogen atom,

R_b denotes a 1-phenylethyl group or a phenyl group wherein the phenyl nucleus is substituted by the radicals R₁ and R₂, whilst

R₁ and R₂, which may be identical or different, each denote a hydrogen, fluorine, chlorine or bromine atom,

X denotes a nitrogen atom,

A denotes an imino group,

B denotes a carbonyl group,

C denotes a -CH=CH-, -C≡C- or -CH=CH-CH=CH- group,

D denotes a methylene group,

E denotes a dimethylamino, diethylamino, Bis(2-methoxyethyl)amino, *N*-methyl-*N*-(2-methoxyethyl)amino, *N*-ethyl-*N*-(2-methoxyethyl)amino, *N*-methyl-*N*-cyclopropylamino, *N*-methyl-*N*-cyclopropylmethyl-amino, *N*-methyl-*N*-(1-methoxy-2-propyl)amino, *N*-methyl-*N*-(2-methoxypropyl)amino or *N*-methyl-*N*-(3-methoxypropyl)amino group,

R_c denotes a cyclopropylmethoxy, cyclobutyloxy or cyclopentyloxy group,

or the tautomers, or stereoisomers or pharmaceutically acceptable salts thereof.

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

Claim 19 (previously presented) The following compound of general formula I according to claim 14:

4-[(3-Chloro-4-fluorophenyl)amino]-6- {[4-(*N,N*-diethylamino)-1-oxo-2-buten-1-yl]amino}-7-cyclopropylmethoxyquinazoline

or a pharmaceutically acceptable salt thereof.

Claim 20 (previously presented) The physiologically acceptable salt of a compound according to one of claims 14 to 19 with an inorganic or organic acid or base.

Claim 21 (previously presented) A pharmaceutical composition comprising a compound according to claim 20, together with an inert carrier and with or without a diluent.

Claim 22 (previously presented) A method for treating a disease comprising administering a pharmaceutical composition according to claim 21, wherein said disease is selected from the group consisting of: malignant tumors, diseases of the airways and lungs and diseases of the gastrointestinal tract and the bile duct and gall bladder.

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

REMARKS/ARGUMENTS

Priority

In the Reply with Amendment Under 37 U.S.C. § 1.111 filed January 8, 2004, applicants requested acknowledgment of the priority claim. As explained in that Reply, the instant application is the national stage of International Application PCT/EP00/05547 (WO 00/78735) filed on June 16, 2000, which claims benefit to prior U.S. Provisional Application 60/146,644, filed July 30, 1999 and prior German Application Nos. DE 199 28 281 and DE 100 23 085, filed June 21, 1999 and May 11, 2000, respectively. Benefit of the earlier filing date of the prior International Application was claimed pursuant to 35 U.S.C. §365(c) on the Declaration for Utility or Design Application, filed on April 25, 2002. In the Office Action mailed April 23, 2004, the Examiner noted that the file was missing certified copies of both the German applications. The priority documents were submitted on October 21, 2004. A copy of the return post card date stamped on October 25, 2004 is enclosed. Applicants submit that the priority is in order and respectfully requests acknowledgment of the priority claim.

Obviousness-type Double Patenting Rejection

In the communication mailed October 12, 2005, the Examiner has withdrawn an obviousness-type double patenting rejection based on 6,627,634. However, the Examiner has maintained a provisional double patenting rejection based on a copending application 10/023,099 ("the '099 application"). Applicants would like to respectfully draw the Examiner attention to the Declaration of Frank Himmelsbach signed on 8 April, 2004 submitted in the copending '099 application. In view of this 1.132 declaration, the Examiner has already removed the obviousness-type rejection in copending application '099. Furthermore, applicants note that "where, through no fault of the applicant, the claims in a later filed application issue first, an obvious-type double patenting rejection is improper, in the absence of a two-way obviousness determination, because the applicant does not have complete control over the rate of progress of a patent application through the Office." See MPEP §804 citing *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir 1991). In view of the foregoing, it is respectfully submitted that the obviousness-type

Application No. 10/016,280
Amdt dated March 13, 2006
Reply to Office action of October 12, 2005

double patenting rejection should similarly be withdrawn in the instant application since a two-way obviousness determination cannot be met for the pending claims of this application. Accordingly, no terminal disclaimer is warranted.

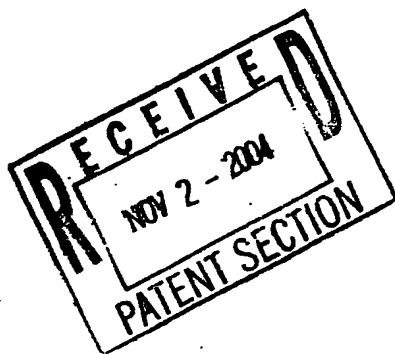
In view of the foregoing, it is respectfully submitted that the subject application is in condition for allowance and such favorable action at an early date is earnestly solicited.

Respectfully submitted,

/Paula K. Wittmayer/

Paula K. Wittmayer
Attorney for Applicant(s)
Reg. No. 53,785

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT. 06877
Tel.: (203) 791-6692
Fax: (203) 798-4408
Dated: March 13, 2006



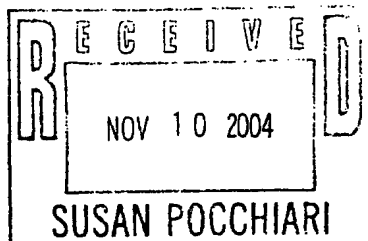
5/1262 ✓ S168

APPLICANT(S): Himmelsbach, et al
SERIAL NO.: 10/016,280
FILING DATE: December 10, 2001
DOCKET NO.: 5/1262
TITLE: Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them

IN CONNECTION WITH THE ABOVE CASE, PLEASE
DATE STAMP TO ACKNOWLEDGE RECEIPT OF THE
DOCUMENTS LISTED BELOW, AND RETURN TO
ADDRESSEE.

1. Reply after Final with Amendment (16 pages)
2. Notice of Appeal (1 page in triplicate)
3. Petition for Extension of Time (1 page in triplicate)
4. Priority Document #199 28 281.1 and #100 23 085.7

Mailed: October 21, 2004



Electronic Acknowledgement Receipt

EFS ID:	1008851
Application Number:	10016280
Confirmation Number:	7351
Title of Invention:	Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them
First Named Inventor:	Frank Himmelsbach
Customer Number:	28505
Filer:	Paula Wittmayer
Filer Authorized By:	
Attorney Docket Number:	5/1262
Receipt Date:	15-MAR-2006
Filing Date:	10-DEC-2001
Time Stamp:	11:35:37
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1	Request for Corrected Filing Receipt	5-1262-Request-Correct-FilingReceipt.pdf	67113	no	2

Warnings:					
Information:					
2	Request for Corrected Filing Receipt	5-1262-Filing-Receipt.pdf	382335	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			449448		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Frank Himmelsbach, et al) Art Unit: 1624
Serial No.: 10/016,280) Examiner: Tamthom Ngo Truong
Conf. No.: 7351)
Filed: December 10, 2001
For: Bicyclic heterocycles, pharmaceutical compositions containing these
compounds, their use and processes for preparing them
Docket No.: 5/1262

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CORRECTION OF FILING RECEIPT

Sir:

The undersigned respectfully requests correction of the Filing Receipt for
Application Number 10/016,280, Confirmation No. 7351.

**Please correct the Domestic Priority data as claimed by applicant to include
—THIS APPLN IS A CONTINUATION OF INTERNATIONAL APPLICATION
PCT/EP00/05547 06/16/2000—, as noted on the attached marked copy of the Official
Filing Receipt.**

Application of Frank Himmelsbach, et al
Serial No. 10/016,280
March 15, 2006

The undersigned hereby requests that the United States Patent and Trademark
Office correct its records accordingly and issue a corrected Filing Receipt.

Respectfully submitted,

/Paula K. Wittmayer/

Paula K. Wittmayer
Attorney for Applicant(s)
Reg. No. 53,785

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March 15, 2006



UNITED STATES PATENT AND TRADEMARK OFFICE

Page 1 of 2
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UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/016,280	12/10/2001	1619	1168	5/1262		11	1

28505
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900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877

CONFIRMATION NO. 7351

UPDATED FILING RECEIPT



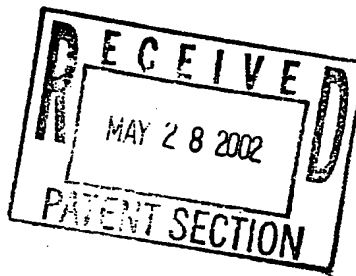
OC00000008178530

Date Mailed: 05/23/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Frank Himmelsbach, Mittelbiberach, GERMANY;
Elke Langkopf, Warthausen, GERMANY;
Thomas Metz, Wien, AUSTRIA;
Flavio Solca, Wien, AUSTRIA;
Birgit Jung, Schwabenheim, GERMANY;
Anke Baum, Alland, AUSTRIA;



Domestic Priority data as claimed by applicant

THIS APPLN IS A CONTINUATION OF INTERNATIONAL APPLICATION PCT/EP00/05547 05/16/2000
THIS APPLN CLAIMS BENEFIT OF 60/146,644 07/30/1999

Foreign Applications

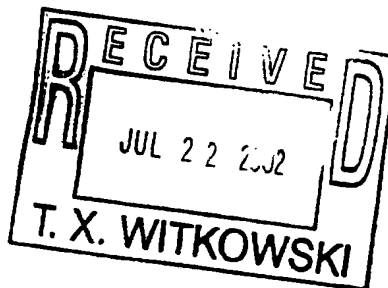
GERMANY 199 28 281.1 06/21/1999
GERMANY 100 23 085.7 05/11/2000

If Required, Foreign Filing License Granted 04/10/2002

Projected Publication Date: 08/29/2002

Non-Publication Request: No

Early Publication Request: No



Title

Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them

Preliminary Class

424

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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PKW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351

28505 7590 04/11/2006

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

Advisory
Action

EXAMINER

TRUONG, TAMTHOM NGO

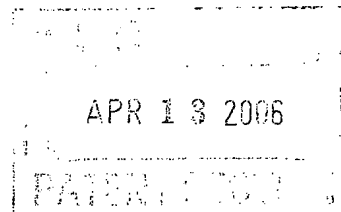
ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/11/2006

3/11/06 Last Day

Please find below and/or attached an Office communication concerning this application or proceeding.



**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/016,280

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 21 and 22.
Claim(s) rejected: 14-20.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: attached Bib. Data Sheet.

ADVISORY ACTION

Applicant's amendment of 3-13-06 has been considered. The request of withdrawing the previous rejection of Obviousness-type Double Patenting (ODP) has not been found persuasive for the following reason:

In applicant's response of 3-13-06, the ODP rejection was traversed on the grounds that the subject matter covered by the claims of the US patent was deemed patentably distinct and thus 2-way obviousness is required. This is not persuasive since the instant application was filed prior to the copending application of 10/ 023,099 (now US 7,019,012).

A review of the MPEP 804, section (a), pp. 88-23, August 2001 Ed. states that **where an application at issue is the earlier filed application, only a one-way determination** (for obviousness) is required **unless two conditions** are met. In the instant case prong A, i.e. sufficient evidence of administrative delay on the part of the PTO, has not been met, and thus, the rejection must be maintained.

Priority

Receipt is acknowledged of priority documents of DE 199-28-281.1 & DE 100-23-085.7 submitted under 35 U.S.C. 119(a)-(d), which documents have been placed of record in the file.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

Application/Control Number: 10/016,280

Page 3

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

3-29-06

 (for SPE
EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Frank Himmelsbach, et al) Art Unit: 1624
Serial No.: 10/016,280) Examiner: Tamthom Ngo Truong
Conf. No.: 7351)
Filed: December 10, 2001
For: Bicyclic heterocycles, pharmaceutical compositions containing these
compounds, their use and processes for preparing them
Docket No.: 5/1262

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CORRECTION OF FILING RECEIPT

Sir:

The undersigned respectfully requests correction of the Filing Receipt for
Application Number 10/016,280, Confirmation No. 7351.

Please correct: the Domestic Priority data to state:

**-- This application is a CON of PCT/EP00/05547 06/16/2000
which claims benefit of 60/146,644 07/30/1999 --**

as noted on the attached marked copy of the Official Filing Receipt.

Application of Frank Himmelsbach, et al
Serial No. 10/016,280
October 6, 2006

The undersigned hereby requests that the United States Patent and Trademark Office correct its records accordingly and issue a corrected Filing Receipt.

Respectfully submitted,

/Paula K. Wittmayer/

Paula K. Wittmayer, Reg. No. 53,785
Attorney for Applicant(s)

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
Tel.: (203) 791-6692
October 6, 2006



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/016,280	12/10/2001	1624	1438	5/1262		11	1

28505
 MICHAEL P. MORRIS
 BOEHRINGER INGELHEIM CORPORATION
 900 RIDGEBURY ROAD
 P. O. BOX 368
 RIDGEFIELD, CT 06877-0368

CONFIRMATION NO. 7351

CORRECTED FILING RECEIPT



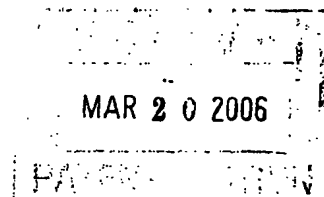
OC000000018304916

Date Mailed: 03/16/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

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 Thomas Metz, Wien, AUSTRIA;
 Flavio Solca, Wien, AUSTRIA;
 Birgit Jung, Schwabenheim, GERMANY;
 Anke Baum, Alland, AUSTRIA;



Power of Attorney:

Robert Raymond-25089
 Mary-Ellen Devlin-27928
 Alan Stempel-28991
 Timothy Witkowski-40232
 Philip Datlow-41482

Anthony Bottino-41629
 Susan Pocchiari-45016

Domestic Priority data as claimed by applicant

This application is a CON of PCT/EP00/05547 06/16/2000
 which claims benefit of 60/146,644 07/30/1999

Foreign Applications

GERMANY 199 28 281.1 06/21/1999
 GERMANY 100 23 085.7 05/11/2000

If Required, Foreign Filing License Granted: 04/10/2002

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/016,280**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

Bicyclic heterocycles, pharmaceutical compositions containing these compounds, their use and processes for preparing them

Preliminary Class

544

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

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NOT GRANTED

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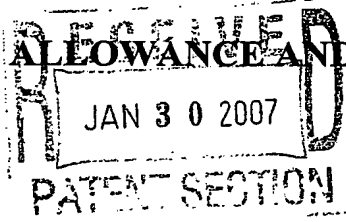
NOTICE OF ALLOWANCE AND FEE(S) DUE

28505

7590

01/24/2007

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368



3.24.2007
4.24.2007

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 01/24/2007

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351

TITLE OF INVENTION: BICYCLIC HETEROCYCLES, PHARMACEUTICAL COMPOSITIONS CONTAINING THESE COMPOUNDS, THEIR USE AND PROCESSES FOR PREPARING THEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$300	\$0	\$1700	04/24/2007

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

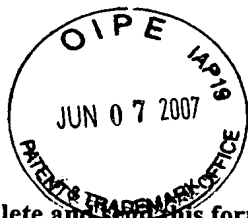
B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.





PART B - FEE(S) TRANSMITTAL

Complete and ~~file~~ this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or **Fax** **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed when appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

28505

7590

01/24/2007

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

_____	(Depositor's name)
_____	(Signature)
_____	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351

TITLE OF INVENTION: BICYCLIC HETEROCYCLES, PHARMACEUTICAL COMPOSITIONS CONTAINING THESE COMPOUNDS, THEIR USE AND PROCESSES FOR PREPARING THEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$300	\$0	\$1700	04/24/2007

EXAMINER	ART UNIT	CLASS-SUBCLASS
TRUONG, TAMTHOM NGO	1624	514-266400

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1	_____
2	_____
3	_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,280	12/10/2001	Frank Himmelsbach	5/1262	7351

28505 7590 01/24/2007
MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 01/24/2007

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.



Notice of Allowability

Application No.

10/016,280

Examiner

Tamthom N. Truong

Applicant(s)

HIMMELSBACH ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE and amdt of 10-6-06.
2. ☒ The allowed claim(s) is/are 14-22.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 9-7-04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JAMES C. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER/1800

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the specification:

Below the title, insert the following sentence:

— This is a continuation of PCT/EP 00/05547 filed on 6/16/00. —

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-6-06 has been entered.

Allowable Subject Matter

Applicant's filing of the terminal disclaimer has overcome the previous rejection of Obviousness-type Double Patenting. Thus, said rejection is now withdrawn.

With no other outstanding rejection, pending claims 14-22 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The invention is drawn to substituted quinazolinyl compounds having two side chains of A-B-C-D-E and R_c. The prior art of record fails to teach or fairly suggest the combination of substituents equivalent to those side chains. The reference of Barth et. al. (US 2004/0158065 A1) teaches related compounds; however, its effective filing date does not antedate the filing date of this application. Therefore, it is not a competent

Art Unit: 1624

prior art.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

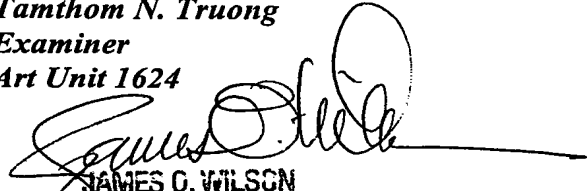
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1-18-07


Tamthom N. Truong
Examiner
Art Unit 1624


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Application/Control Number: 10/016,280

Page 2

Art Unit: 1624

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the specification:

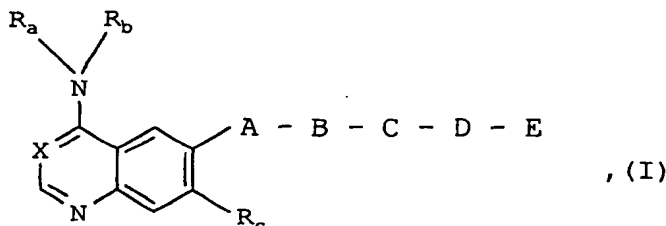
Below the title, insert the following sentence:

– This is a continuation of PCT/EP 00/05547 filed on 6/16/00. –

*Please
enter
TNT
1/18/07*

BICYCLIC HETEROCYCLES, PHARMACEUTICAL COMPOSITIONS
CONTAINING THESE COMPOUNDS,
THEIR USE AND PROCESSES FOR PREPARING THEM

*am
ind.*
This is a continuation of PCT/EP 00/05547 filed on 6/16/00.
5 The present invention relates to bicyclic heterocycles of general formula



the tautomers, the stereoisomers and the salts thereof, particularly the physiologically acceptable salts thereof with inorganic or organic acids or bases which have valuable pharmacological properties, particularly an inhibitory effect on signal transduction mediated by
10 tyrosine kinases, the use thereof for treating diseases, particularly tumoral diseases, diseases of the lungs and respiratory tract, and the preparation thereof.

In the above general formula I:

15 R_a denotes a hydrogen atom or a C_{1-4} -alkyl group,

R_b denotes a phenyl, benzyl or 1-phenylethyl group wherein the phenyl nucleus is substituted in each case by the groups R_1 to R_3 , whilst

20 R_1 and R_2 , which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom,

a C_{1-4} -alkyl, hydroxy, C_{1-4} -alkoxy, C_{3-6} -cycloalkyl, C_{4-6} -cycloalkoxy, C_{2-5} -alkenyl or C_{2-5} -alkynyl group,

25

an aryl, aryloxy, arylmethyl or arylmethoxy group,

a C_{3-5} -alkenyloxy or C_{3-5} -alkynyloxy group, whilst the unsaturated moiety may not be linked to the oxygen atom,

Notice of References Cited	Application/Control No. 10/016,280	Applicant(s)/Patent Under Reexamination HIMMELSBACH ET AL.	
	Examiner Tamthom N. Truong	Art Unit 1624	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2004/0158065	08-2004	Barth et al.	544/284
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

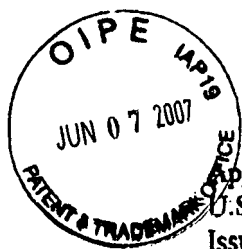
*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

2/18/07



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Himmelsbach, Frank et al.) Art Unit: 1624
U.S. Patent No. : 7,220,750) Examiner: Truong, Tamthom N.
Issue Date : May 22, 2007
U.S. Appln. No. : 10/016,280
U.S. Filing Date : December 10, 2001
Title of Invention : Bicyclic Heterocycles, Pharmaceutical Compositions containing these
Compounds, Their Use and Processes for Preparing Them
Attny. Docket No. : 5/1262

June 6, 2007

Commissioner for Patents
Office of Patent Publication
ATTN: Certificate of Correction Branch
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION

Sir:

The undersigned respectfully requests the issuance of a Certificate of Correction for the U.S. Patent No. 7,220,750 to correct the error indicated below.

On Page 1 of the patent under the heading Related U.S. Application Data, please correct the entry to read:

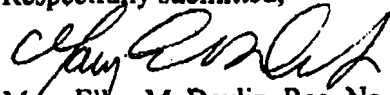
Continuation of Application No. PCT/EP00/05547, filed June 16, 2000, which claimed the benefit of Provisional Application No. 60/146,644, filed July 30, 1999, and German Application Nos. DE 199280281.1 and DE 10023085.7, filed June 21, 1999 and May 11, 2000, respectively.

In conjunction with this request for a Certificate of Correction, Applicants' attorney has also filed a petition to correct the claim of benefit under CFR § 1.78.

The undersigned hereby requests that the United States Patent and Trademark Office correct its records accordingly and issue a Certificate of Correction.

If it is determined that a fee is due in connection with this submission, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 02-2955.

Respectfully submitted,



Mary-Ellen M. Devlin, Reg. No. 27,928
Attorney for Applicant(s)

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877
Tel: (203) 798-4866
Date: June 6, 2007

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

Page 1 of 1

PATENT NO. : 7,220,750
APPLICATION NO.: 10/016,280
ISSUE DATE : May 22, 2007
INVENTOR(S) : Frank Himmelsbach, et al

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Page 1 of U.S. Patent No. 7,220,750, under the heading Related U.S. Application Data, please correct the entry to read:

Continuation of Application No. PCT/EP00/05547, filed June 16, 2000, which claimed the benefit of Provisional Application No. 60/146,644, filed July 30, 1999, and German Application Nos. DE 199280281.1 and DE 10023085.7, filed June 21, 1999 and May 11, 2000, respectively.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Michael P. Morris, Esq.
Boehringer Ingelheim Corporation
900 Ridgebury Road, P. O. Box 368
Ridgefield, CT 06877-0368

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.